MONITORING INTRA-ABDOMINAL PRESSURE

DURING PHYSICAL ACTIVITY

by

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ABSTRACT

Pelvic floor disorders (PFD) affect one in four women in the United States. Elevated intra-abdominal pressure (IAP) during daily activity or strenuous physical activity has been identified as a risk factor in the prevalence of PFD. However, the relationship between IAP and physical activity remains poorly understood. Despite the lack of scientific evidence, clinicians oftentimes prescribe long-term activity restrictions to urogynecologic postoperative patients to minimize IAP, which is thought to lessen the load on the pelvic floor. Since many health benefits are associated with exercise, it is necessary to understand how IAP changes with activity in order to reduce risk to the pelvic floor while allowing women to be physically active. Current methods of measuring IAP include invasive catheters in the vagina, rectum, bladder, or stomach that are tethered to laboratory equipment and have been shown to have poor dynamic response. These characteristics limit the potential for tracking IAP during daily physical activity away from the clinic. The objectives of this research were to determine how intra-abdominal pressure changes during activities of daily living and exercise and to develop a IAP exercise routine that may be adapted for postsurgical patients. Three phases of this work included (1) development of a wireless gel-filled intravaginal pressure sensor to accurately track intra-abdominal pressure, (2) testing the newly developed intravaginal sensor in benchtop and in vivo settings to determine the utility of sensors in real-world

deployments, and (3) using the wireless intravaginal pressure sensor to characterize IAP during exercise and, based upon results, create a low intra-abdominal pressure routine that can be used to exercise while minimizing pressure load on the pelvic floor.

I dedicate this work to my parents, Scott and Suzy Coleman,

and friends David Parkinson and Dannielle Holder

for their love and support

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CHAPTER 1

INTRODUCTION

1.1 Introduction

Pelvic floor disorders (PFD) affect one in four women in the United States and have been referred to as a hidden epidemic [1], [2]. A pelvic floor disorder results from a weakening of pelvic floor muscles and remodeling of connective tissue. This weakening can cause lifestyle-altering symptoms such as urinary or fecal incontinence and pelvic organ prolapse (POP) in which women experience herniation of the pelvic viscera [3]–[5]. Elevated intra-abdominal pressure (IAP) during daily activity or strenuous physical activity has been identified as a risk factor for PFD, but our understanding of this relationship has been hampered by the current methods of monitoring IAP in a laboratory environment [6], [7]. Due to the lack of monitoring capability outside of the laboratory, the relationship between IAP and physical activity is poorly understood. Despite the lack in scientific evidence, activity restrictions are often prescribed by physicians, which vary widely in limitation and duration in an effort to minimize IAP and the load on the pelvic floor [8]–[11]. The most common activity restrictions include lifting, stair climbing, work activities, and exercise [12], [13]. FitzGerald et al. stated the social and economic impact of postoperative activity restrictions have yet to be studied, but it is conceivable that a

middle range of activity may be beneficial to connective tissue remodeling and avoiding muscle atrophy [12]. Given the health benefits of exercise, including a significant reduction in hypertension [14], coronary artery disease [15], depression [16], and type II diabetes [17], patients should be encouraged to be physically active.

Current methods of measuring IAP include the use of invasive catheters in the vagina, rectum, bladder, or stomach, all of which require bulky laboratory equipment, limiting the measurements to those activities that can be performed while tethered to the clinical instrument [8], [18]–[21]. There are two categories of clinical intra-abdominal pressure measurement devices: sensor-tipped catheters and fluid-coupled transducers. Sensor-tipped catheters are designed to place the sensor, located at the catheter tip, directly at the physiologic site of interest. Sensor-tipped catheters are more accurate than fluid-coupled transducers [22]; however, they require a fluid filled environment, such as the bladder or urethra, for accurate pressure measurements [23], [24]. As a result, sensor-tipped catheter systems are typically employed in the bladder, but fluid volume must be tightly controlled making IAP monitoring during daily activity impractical [25].

Fluid coupled transducers utilize noncompressible fluids, such as saline, to transmit pressure from the physiologic site of measurement to an externally located sensor. Typically these systems deploy inflated balloons, which allow pressure measurements to be made in nonfluid filled environments such as the vagina or rectum. The length of the tubing, presence of air bubbles in the tubing, and transducer type can have a substantial effect on the measurement accuracy [26]–[29]. Additionally, damping and resonance effects of these systems are dependent on component characteristics such

as the length, diameter, presence of air bubbles in the line, and stiffness of the tubing connecting the sensor to the site of measurement [22], [25]. Therefore, care must be taken to not only set up the system but also to interpret the data and understand the limitations of these systems due to their poor dynamic response during rapid changes in pressure [30]. Nonetheless, this technique is the preferred method for measuring IAP during static conditions such as under standard urodynamic laboratory procedures. Given the difficulty of use, physiologic site restrictions, and dynamic response and accuracy limitations of current methods to monitor IAP, there is a need for a new system to monitor IAP during exercise.

The objectives of the work presented in this dissertation were to measure intra-abdominal pressure changes during various activities both inside and outside of the clinic and to develop a low intra-abdominal pressure exercise routine that may be adapted for patients recovering from pelvic floor surgery. The objectives of this work were accomplished through three research phases:

1) Development of a wireless gel-filled intra-abdominal pressure sensor to accurately track intra-abdominal pressure.
2) Testing the accuracy of the newly developed wireless intravaginal transducer in both benchtop and in vivo settings to verify and validate the use of these sensors for measuring IAP outside of the clinic.
3) Use the wireless intra-abdominal pressure sensor to characterize IAP during activities of daily living and exercise and use the wireless sensor to develop a low intra-abdominal pressure exercise routine that postsurgical patients can

utilize to stay active while minimizing the pressure induced loading on the pelvic floor.

To provide conceptual framework for this work, the anatomy and physiology of the pelvic floor, a background on pelvic floor disorders, the role that intra-abdominal pressure plays in pelvic floor disorder, and current methods for monitoring intra-abdominal pressure are reviewed.

CHAPTER 2

BACKGROUND

2.1 Evolutionary Significance

Modern day humans, through the course of evolution, selected bipedalism as the primary form of locomotion. A number of mammals, such as bears and meerkats, will occasionally walk upright but only humans are obligate bipeds [31], [32]. The evolutionary push towards bipedalism required the adjustment of the pelvic floor muscles, from originally flexing and abducting the tail, to a supportive role. Since modern day humans have assumed an upright posture, the muscles and connective tissue of the pelvic floor have shifted roles to support the abdominal viscera, which was once supported by the abdominal wall during quadrupedalism [32], [33].

2.2 Structure and Function of the Pelvic Floor

The pelvic floor can be divided into active and passive structures that support the abdominal viscera and maintain continence [34]. Passive support consists of the pelvis bone and surrounding connective tissue. The pelvis includes major anchoring points for the pelvic floor muscles including the pubic ramus, ischial spines, and the sacrum. The pelvis consists of two innominate bones (hip bones) that are fused to the sacrum

posteriorly and each other anteriorly at the pubic symphysis. Each bone is composed of the ilium, ischium, and pubis bones, which are connected by cartilage in youth but fused together later in life [35]. The pelvis is separated into the greater pelvis and the minor pelvis. The greater (major pelvis) pelvis is enclosed by the pelvic girdle and the pelvic brim and by the ilium on either side and is occupied by the abdominal viscera. The lesser pelvis (minor pelvis) is the space between the pelvic inlet and pelvic floor and contains the sexual organs, rectum, and bladder. Abnormalities or injuries in the pelvic structure have been shown to impact long-term pelvic floor function but have been reported as rare occurrences [34]. When compared to the male, the shape of a female pelvis is wider in diameter and circular shaped to facilitate childbirth, which may play a role in the development of a pelvic floor disorder (PFD) [33], [36].

The muscles that make up the pelvic floor include the coccygeus and levator ani muscles that are attached to the inner surface of the minor pelvis. The levator ani, coccygeus, and fascia combine to form the pelvic floor [37]. The posterior section of the pelvic diaphragm consists of the coccygeus muscle and is positioned on the anterior surface of the sacrospinous ligament [36]. The levator ani muscles play a critical role in supporting the pelvic organs while protecting the pelvic connective tissues from excess load [37]. The levator ani muscle is on average 9.3-mm thick and comprised of three major muscles: the pubococcygeus (pubovisceral), iliococcygeus, and puborectalis muscles [37]–[39]. The iliococcygeus muscle is a thin section of the levator ani that originates from the arcus tendineus of the levator ani to the ischial spine and posteriorly attaches to the last two segments of the coccyx. Bilaterally the Iliococcygeus muscles converge to form a

raphe and contribute to the anococcygeal ligament. The pubococcygeus muscle is the medial muscle that originates from the back of the body of the pubis and anterior portion of the arcus tendineus [36]. The iliococcygeus and the posterior fibers of the pubococcygeus muscles meet to form the levator plate, which supports the pelvic organs. When the body assumes an upright posture, the levator plate is horizontal and supports the rectum and the upper two-thirds of the vagina [36], [40], [41].

Nerve innervation of the levator ani muscles is primarily from the third and fourth sacral nerve roots via the pudendal nerve [37]. The majority of the muscle fibers in the levator ani are slow-twitch fibers (type I) that function to maintain constant tone. In the periurethral and perianal areas, the levator muscles show an increased density of fast-twitch (type II) fibers. This arrangement suggests that the levator ani muscle maintains tone to support the abdominal viscera while voluntary squeezing of the puborectalis may increase the tone, thereby countering increases in intra-abdominal pressure [36].

Connective tissue covering the superior and inferior surfaces is called the superior and inferior fascia of the levator ani [37]. The arcus tendineus of the levator ani is a dense connective tissue structure that runs between the pubic ramus to the ischial spine and follows along the surface of the obturator internus muscle [36]. The arcus tendineus fasciae pelvis are tensile structures bilaterally on both sides of the urethra and vagina. The structure acts like a cable of a suspension bridge that is supported at each end to the pelvis and provides attachment points along its length to suspend the urethra on the anterior vaginal wall. The arcus tendineus fascia pelvis becomes a broad structure as it passes dorsally to insert into the ischial spine. The arcus tendineus appears as a sheet of

fascia as it fuses with the endopelvic fascia and merges with the levator ani muscles [37].

The opening where the urethra and vagina pass through the pelvic floor is called the urogenital hiatus of the levator ani muscles. The levator ani muscle keep the urogenital hiatus closed by compressing the vagina, urethra, and rectum against the pubic bone, pelvic floor, and organs in the superior direction. The ischiocavernosus and bulbocavernosus muscles make up the inferior aspect of the urogenital diaphragm, which closes the urogenital hiatus. Additionally these structures have a sphincter-like effect at the distal vagina, contribute to continence, and provide structural support for the distal urethra [34].

The levator ani muscles provide constant muscle tone to prevent openings in the pelvic floor where prolapse could occur [37]. As long as the levator ani muscles are functioning properly to support and maintain closure of the genital hiatus, the ligaments and fascial structures supporting the pelvic organs will be under minimal tension and act only to stabilize their position above the levator ani muscles. When the levator ani muscles relax or are damaged, the pelvic floor opens, shifting pelvic floor support from the levator ani to the suspensory ligaments and fasciae. The suspensory ligaments and fasciae, which are not intended to sustain an increased load, may fail and lead to prolapse [37]. The loss of primary support from the levator ani may also cause the sling behind the anorectum to loosen, which results in levator plate sag and the opening of the urogenital hiatus [42]. This disease pathology has been documented in women with prolapse as they were observed to have enlarged urogenital hiatus upon clinical examination [43].

2.3 Pelvic Floor Disorders

The female pelvic floor structures are normally balanced to allow childbirth and waste to be eliminated though urination while preventing incontinence and pelvic organ prolapse [37]. Pressures in the bladder change by approximately 12 cm H_2O from lying down to standing position. Likewise, the intraurethral pressures increase by 19 cm H_2O during the same movement, allowing the women to maintain continence. The difference in pressure between the bladder and the urethra during an activity is a result of coordinated reflexes in muscles and connective tissues in the pelvic cavity [34]. When the pelvic floor is functioning improperly, three primary disease pathologies occur: pelvic organ prolapse, urinary incontinence (UI), and fecal incontinence [2], [44].

Pelvic organ prolapse (POP) is defined as the downward descent of the pelvic organs such as the small intestine into the vagina (enterocele), bladder into the vagina (cystocele), rectum into the vagina (rectocele), or uterus into the vagina (uterine prolapse) [45], [46]. POP occurs when pelvic organs can no longer be supported by the pelvic floor and are displaced from their normal anatomical location and in severe cases protrude to the outside of the vagina [47]. Hendrix et al. found that 41.1% of 16,000 women examined had some form of prolapse. In this study cystocele occurred most often, 34.3% followed by rectocele at 18.6% and 14.2% having uterine prolapse [1]. Prolapse severity is determine by the Pelvic Organ Prolapse Quantification (POP-Q) method developed in 1996 by the International Continence Society [48]. The POP-Q consists of six vaginal measurements in relation to the hymen during a Valsalva maneuver with proximal measurements being negative and distal being positive [48], [49]. Measurements of the

leading edge of prolapse are used to determine the degree of prolapse, which ranges from Stage 0 (no demonstrated prolapse) to Stage IV (total length eversion of the lower genital tract) [48], [49]. Despite the quantification system, it is unclear at what point POP-Q measurements represent a deviation from normal uterovaginal support, although most would agree that prolapse beyond the hymen is clinically significant [47]. Some of the clinical presentations of POP include urinary urgency or frequency (87%), constipation (67%), visual prolapse (43%), pelvic heaviness (56%), difficulty emptying bladder (49%), and fecal incontinence (31%), among others [50].

One of the more frequently occurring pelvic floor disorders is urinary incontinence (UI) with prevalence rates between 8.5% to 38% depending on age, number of >20-week births and definition [51], [52]. Stress incontinence, the most common type of UI, is the involuntary leakage during effort or exertion [53]. Urge UI is the involuntary leakage accompanied by or immediately proceeded by urgency, while mixed UI is the involuntary leakage associated with urgency and exertion [54], [55]. Urinary incontinence is most often diagnosed based on history alone, utilizing volume charts and bladder diaries [56]. Confirmatory tests including a general examination in which cognitive status and peripheral oedema is accessed, abdominal exam, and testing by Urodynamic cystometry can supplement the patient history and physical exam [56]. Urinary continence is based upon the principle in which urethral closure pressure must be greater than bladder pressure at rest and during increasing IAP to maintain continence [37]. The decrease of urethral closure pressure is related to the loss of the total number of striated muscle fibers, which from years 15 to 80 is around 2% per year [24]. Despite the muscle fiber loss,

exercise regiments of women aged 75 or older have been shown to increase pelvic floor strength by about 30% after an intensive 8–12 week resistance training regimen [57]. Many studies have shown that urinary incontinence is associated with fecal incontinence in urogynecologic patients suggesting a common link in progression [58].

2.4 Pelvic Floor Disorder Prevalence

According to a 2005–2006 National Center for Health study, nearly 24% of U.S. women are affected with a primary or recurrent pelvic floor disorder (PFD) in the United States, which has been referred to as a hidden epidemic by clinicians and in popular media [1], [2], [59], [60]. In the year 2000, pelvic floor disorders accounted for $14.7 billion dollars spent directly in the diagnosis and treatment of PFD [61]–[64]. The prevalence rate around the world can vary with region and ethnicity, but Australia (35.3%), France (27.5%), and 24.6% in Norway have rates comparable to the United States [65]–[67]. The future outlook of pelvic floor disorders in the US remains grim. Over the next 30 years, the demand for PFD care is expected to increase two-fold over the rate of the same population in the USA [64]. As the baby bomber population ages, the number of adults over 65 is expected to double from 38.7 million to 88.5 million by the year 2050. Pelvic floor disorders over the same time period are projected to increase between 46%–59% [61].

2.5 Pelvic Floor Treatments

There are five treatment options for women with a PFD, including expectant management, prescribed medication and lifestyle interventions, pelvic floor muscle training (PFMT), pessary use, and surgical intervention.

Expectant management is an observational approach for individuals with mild prolapse, which includes regular checkups while withholding more invasive treatment options [68]. Patients are more likely to choose expectant management over pessary use when experiencing pelvic or lower back pain. However, as PFD severity increases, patients are more likely to choose pessary or surgery over expectant management [69].

Prescriptive intervention for treatment of PFD includes lifestyle interventions, voiding regiments, and the use of stool softeners, all in an effort to reduce straining on the pelvic floor [70]. Lifestyle modifications include losing weight, eating a high fiber diet, and avoiding heavy lifting [71]. The effectiveness of these prescribed interventions are less clear, as no study to date has reported on pelvic floor health after lifestyle modifications [47]. It was reported in one study of 73 women that straining during defecation as a young adult was more typical in women that developed POP and UI than those that did not (61% vs 4%, $p < 0.001$) [72]. However, this is less clear in larger studies. A study by Jelovsek et al. in 2005 found a large prevalence of constipation with women with POP and UI, but most associations between bowels symptoms and POP were weak [73]. In a study by Kahn et al. in 2005, only a weak association was found between POP-Q scores and bowel symptoms [74]. Medical prescriptions for urinary incontinence include anticholinergic drugs designed to inhibit parasympathetic nerve impulses to control urge

urinary incontinence [75]. Drugs prescribed in this category include Oxybutynin, Tolterodine, Darifenacin, Solifenacin, Trospium, and Fesoterodine. Some of these drugs are available in extended release form, requiring taking the medication once a day orally. Others are immediate release drugs requiring multiple doses a day [76].

Pelvic floor muscle training (PFMT) consists of exercises aimed to increase pelvic floor muscle tone and alleviate symptoms of a pelvic floor disorder. PFMT requires training by a clinician or physical therapist, sometimes aided with biofeedback or digital palpation, on the proper exercise techniques to engage and strengthen the pelvic floor muscles [77], [78]. Pelvic floor muscle training has been shown effective at reducing the frequency and amount of UI episodes in sport students [79]. Several other studies have found PFMT to be effective in preventing or improving stress urinary incontinence [80]–[82].

The biological rationale for PFMT effectiveness are 1) contracting the pelvic floor before a forceful activity (the Knack) has been shown to reduce the amount of urine leakage of older women with mild to moderate stress urinary incontinence [83]; 2) strength training builds muscle volume, stiffness, and structural support of the pelvic floor, which elevates the levator plate; and 3) pelvic floor muscles are indirectly trained and strengthened by performing abdominal wall muscle exercises [84]. Although PFMT has been shown effective in the treatment of UI, many exercise routines exist, and an optimized protocol has yet to be developed [78], [85]. It is less clear if PFMT assists in alleviating symptoms of POP. In 2009, Hagen et al. showed a 16-week PFMT regiment improved symptoms and POP-Q scores in a randomized trial of 47 women with stage 1 or

2 POP [86]. In another study performed by Piya-Anant et al. in 2003, PFMT was shown to be effective in severe but not mild prolapse, but results in this study should be viewed with caution as many pitfalls were present, suggesting that additional research is needed to ascertain the benefits of POP [87], [88].

Pessaries are vaginal devices made of plastic or silicone that provide pelvic floor and pelvic organ structural support. Pessaries are generally reserved for women waiting for surgical repair or considered poor surgical candidates, including those who are interested in having children, after unsuccessful surgical repair, and for women who prefer management over surgical correction [89], [90]. In general, 50% of patients will chose to use pessaries as an alternative to surgery, 25% will choose surgery after pessary use, and 20% will choose expectant management [91]. Two primary factors influence successful pessary placement: a wide vaginal hiatus and short vaginal length [92]. Pessary user fit is approximated by width and length of the vagina and is determined by trial and error [90].

Supportive and space-occupying pessaries are used but depend on the prolapse type and severity. Supportive pessaries rest under the symphysis and sacrum, elevating the vagina and include the Gehrung, Hodge, Shaatz, rings, doughnuts, and ovals [89], [93]. The doughnut pessary is most commonly used for third-degree posterior prolapse, while ring pessaries are used more to treat anterior and apical defects. The Gehrung pessary is used for cystoceles and rectoceles, while ring pessaries are primarily used in stage II and III prolapse [92]. Space occupying pessaries include the cube, Gellhorn, and inflatoball and are used in cases where there is poor pelvic floor strength, wide pubic arch, or increased

prolapse severity [93]. Gellhorn pessary is used more with stage IV prolapse, while the cube is used for women awaiting surgical repair with third degree prolapse [92]. Pessary devices are also used to treat stress urinary incontinence. These devices are primarily ring shaped and provide support by bracing against bladder neck. Devices in this category include the Conveen Continence Guard, PelvX ring, various incontinence dishes, and even a contraceptive diaphragm or short menstrual tampon can be used [93].

The use of pessaries to treat POP and UI have been shown successful in research studies. Handa and Jones in 2002 found out of 56 women, POP improved in 21%, and the stage of POP did not worsen in any participant using POP-Q quantification after 1 year of pessary use [94]. Likewise, pessaries were found to be effective for treatment of urge urinary incontinence and mixed urinary incontinence [95]. Additionally it was found that continued pessary use improved user symptoms and patient satisfaction [96], [97].

The risk for pelvic floor surgery in the general population varies with age, but estimates place the lifetime risk at 11.1% for UI and POP surgery [98]. Of the women who undergo surgery, 30% will return for surgical revision within 5 years of the initial repair [99]–[101]. According to Boyles et al. (1997), the number of women that underwent an inpatient surgical procedure for POP and urinary incontinence was 84,000 and 200,000 respectively [100]–[102]. The age adjusted rate of POP and UI surgery for women over 50 was 3.3 and 1.5 cases per every 1000 women, respectively [100], [101]. Since UI and POP are closely related, the percentage of surgeries that encompass both domains range from 10.6%–21% [100], [102]. Patients with a history of prior prolapse surgery were 77% more likely to choose surgery over pessary when all treatment options are considered [69]. It is

well known that the rate of surgical reoperation for PFD is high. A report from the Kaiser Permanente Group found the rate of POP and UI reoperations to be 29% [103]. In the study by Clark et al. in 2003, it was found that the risk of reoperation was high, between 13%–17%, with 60% of reoperations being performed at the same anatomic site as the primary operation suggesting failure of the initial repair [104]. Despite the high surgical and revision rates, there are few options for women other than surgery once POP and UI become severe.

Two types of surgery methodologies exist for the treatment of POP. They include reconstructive and obliterative surgery. Reconstructive surgery aims to correct the prolapse while maintaining sexual function, while obliterative surgery replaces the pelvic viscera in the pelvic cavity before closing off the vagina canal. Reconstructive surgery aims to correct the PFD while preserving sexual and in some cases reproductive function, while obliterative surgery is reserved primarily for the elderly who are no longer sexually active [47]. Reconstructive surgery can be used to treat many pelvic floor disorders including anterior colporrhaphy, paravaginal repair, posterior colporrhaphy, vaginal hysterectomy, abdominal hysterectomy, and vaginal enterocele repair, as well as others [103].

Surgical treatment of POP of the uterus of the vagina primarily consists of abdominal sacrocolpopexy, but its designation as criterion standard has been questioned recently [105]–[107]. Sarcolpopexy is performed through abdominal incisions using either laparoscope or with a surgical robot under general anesthesia. A graft of synthetic mesh is attached to the front and back surfaces of the vagina and anchored to the sacrum. The graft is then covered by the peritoneum, which prevents adhesion and erosion of the bowl

[108], [109]. This procedure has been found to have superior outcomes compared to other vaginal procedures including sacrospinous colpopexy, uterosacral colpopexy, and transvaginal mesh, but anatomic support deteriorates over time [105], [107].

Many surgical procedures exist for the treatment of urinary incontinence, including retropubic suspensions and slings that improve bladder neck support [110], [111]. Retropubic suspensions are performed by attaching the vaginal wall by permanent sutures to the pectineal ligament next to the pubic bone [110]. This procedure can be performed using autologous fascia, cadaveric tissue, and synthetic material. Two relatively new surgical procedures were introduced to treat stress urinary incontinence, including the tension-free vaginal tape (TVT) procedure in 1996 and the transobturator technique in 2001 [111]. The TVT procedure involves tiny incisions in the abdomen and vaginal wall where a sling is placed below the urethra to keep its normal position [112]. This procedure has been found safe and effective with an 86% cure rate and 11% improvement rate with low complication risk [113], [114]. Similarly the transobturator technique is designed to reproduce the natural suspension of the urethral fascia while avoiding bladder injuries of Retropubic needle passage [115], [116]. All three of these procedures work by decreasing the urethral closure pressure needed to overcome bladder pressure to maintain continence [37]. An alternative surgical treatment for older and frail women include injecting collagen, silicon, or carbon beads into the periurethral tissue at the bladder neck to decrease urethral closure pressure. This procedure is usually carried out using local anesthetic in an outpatient setting. Although the cure rates are lower and may require multiple injections over time, urethral injections provide an

alternative to surgical repair [56].

Each year, between 500,000 to 650,000 women undergo a hysterectomy, which is considered the most frequently performed nonpregnancy gynecological procedure [117]–[119]. Hysterectomy is the removal of the uterus, through the vagina or through the abdomen, performed either open or by laparoscopic means. The most common indications for hysterectomy include the presence of a benign smooth muscle tumor called a fibroid (38.5%), menstrual disorders (35.3%), and prolapse, which accounts for 6.5% to 11% of procedures performed [120], [121]. Although hysterectomies are performed for POP, the surgical procedure has been implicated as a risk factor for the development of a primary of recurrent PFD. However, a prevalence study in 2002 found women with a uterus to have a slightly higher odds ratio compared to those without a uterus for risk of developing POP, suggesting possible repair of the pelvic floor during the hysterectomy [1]. Results of this study must be interpreted with caution as it did not record the initial indications for the hysterectomy. In another study, the risk of pelvic floor reoperation was 5.5 times higher in women having previously undergone a hysterectomy for prolapse than having had a hysterectomy for other reasons [122]. Additionally, a Swedish study found UI to be more prevalent in women with a hysterectomy [123]. The risk of surgical repair after hysterectomy is 1% in 3 years, rising to 5% after 15 years [122].

2.6 Risk Factors

There are a variety of risk factors contributing to the incidence and progression of PFDs. Risk factors can be categorized into two groups: nonmodifiable and modifiable.

Nonmodifiable risk factors are inherent to the individual and include age [62], [63], [111], race [1], genetics [125], [126], and childbirth [122], [126], [127]. Lifestyle choices of the individual including occupation, obesity, and strenuous physical activity are the modifiable risk factors for PFD [58], [67], [126], [128], [129]. Popular belief and scant clinical data suggest that strenuous physical activity increases intra-abdominal pressure (IAP), which in turn increases the load on the pelvic floor [6], [7], [18], [44]. Due to the assumed relationship between IAP and activity, clinicians often recommend drastic long-term activity restrictions for women with existing PFD or after surgical repair [8], [9] to minimize increased IAP, which is thought to increase the breakdown of surgical repair [9]. Postsurgical activity restrictions include lifting more than 10–20 lbs, climbing stairs, exercising, driving, housework, coitus, bathing, and using tampons or douches [9], [12]. Although there is some consensus in the field of which activities to restrict, the duration varies widely [12]. In general, the activity restrictions prescribed are based upon individual viewpoints [10]–[12]. In contrast to the current clinical practice, one study discussed the possibility that exercise has the potential to lower the risk of pathologies such as pelvic floor disorders [8]. Given the benefits of exercise, including a significant reduction in hypertension [14], coronary artery disease [15], depression [16], and type II diabetes [17], women should be encouraged to be maximally active.

There is a need to correlate elevated IAP during activity with the progression, recurrence, and the incidence of PFD. The first step in realizing this goal is to accurately track IAP during daily activity. Once quantification of activities is recorded, investigators can begin to modify prescribed activity restrictions and determine the effects on PF health

or the risk of developing a pelvic floor disorder. The short term goal of monitoring IAP during exercise is to understand how IAP relates to the type of activity performed. This is beneficial in the short term to overturn postsurgical and prescribed activity restrictions.

2.7 Sensors and Physiologic Pressure Measurements

All sensors can be categorized as either chemical or physical. Chemical sensors are used to detect concentration, or presence, of a compound and monitor chemical activity in both diagnostic and therapeutic settings. Chemical sensors include gas sensors, photometric systems for detecting concentration, electrochemical sensors such as pH sensors, and bioanalytic sensors, which include enzyme substrate and antigen-antibody interactions [130]. Physical sensors include geometric, mechanical, thermal, and hydraulic sensors used to measure muscle displacement, blood pressure, body temperature, blood flow, and bone growth.

A biosensor is a probe that registers biological changes. Most often the biosensor is directly connected to a transducer or it directly transduces the primary measurement into a secondary signal [131]. As an example, pressure applied to a piezoresistive pressure transducer is transferred to a mechanical force by the transducer membrane. The flexing of the silicon membrane changes the resistance of the sensing element arranged around the membrane and turns the mechanical stress to an electrical signal. Physiologic pressure measurement systems typically employ electromechanical transducers that convert pressure into an electrical signal that can be processed, displayed, and stored [132]. These electromechanical systems are comprised of linear and angular displacement

sensors and are based upon changes in inductance, capacitance, or resistance.

Inductance sensors, work by first separating coils from each other and applying an AC current to one while measuring the change in current in the other. The changing distance between two coils results in a nonlinear change in the current of the monitored coil. However both coils must remain coaxial because the system is unable to distinguish between transverse movement to movement within the same plane [130].

The simplest form of a capacitive sensor is a parallel place capacitor. Two plates are charged in a circuit where the capacitance is determined by (2.1), where ε is the dielectric constant of the material between the plates, d is the distance between plats, and A is the cross-sectional area of the plates.

$$c = \varepsilon \frac{A}{d} \tag{2.1}$$

As the distance between the plates is changed, while keeping the overlapping area fixed, the sensor will produce a hyperbolic change in capacitance. Modifications to this original design include changing the dielectric material between plates, changing the area of the plates, or connecting multiple plates in series or in parallel.

Resistive sensors typically include variable resistance sensors and resistive strain gauges. Variable resistance sensors work by changing the placement of a sliding tap on a resistive element. These circuits can be measured by applying a known current through the resistive elements and while measuring the resulting voltage or with the use of a voltage divider. Resistive strain gauges are based upon an electrical conductor such as a piece of metal, metal foil, or fine gauge wire that is stretched within its elastic limit. This stretching increases the material length while decreasing the cross-sectional area, which

changes the resistance based upon (2.2):

$$R = p\frac{l}{A} \tag{2.2}$$

where R is the resistance, p is the material electrical resistivity, l is the length of the wire, and A is the cross-sectional area. The stretching of the electrical conductor will only result in a very small change in resistance. Additionally, strain gauges are highly susceptible to temperature changes, which alter the resistance of the conductive material, which can be on the same order of magnitude as the change due to strain. To overcome these challenges, stain gauges are arranged in a Wheatstone bridge configuration where sensitivity is doubled or quadrupled depending on bridge design. However, this configuration presents a challenge as the material that the strain gauge is attached to as well as the strain gauge itself have independent temperature coefficients of expansion. To circumvent this problem, the strain gauge and attached material are engineered to have identical temperature coefficients of expansion [130]. Alternatively, a strain gauge can be utilized to monitor temperature changes so temperature coefficients of offset and sensitivity can be compensated for.

2.8 Measuring Intra-abdominal Pressure

Intra-abdominal pressure research began as far back as 1851 when Weber observed that arterial pulse changed with respiratory effort [133]. Since then, intra-abdominal pressure has been routinely monitored in gynecological and surgical settings [25], [134]. Various methods have been developed to measure intra-abdominal pressure. Direct IAP measurement can be achieved through the pelvic cavity, but this requires

invasive cannulation through the abdominal wall [135]. Less invasive, indirect measurement of IAP can be performed in the vagina, bladder, rectum, or the stomach [25], [136]–[139].

The clinical standard for physiologic measurements are typically achieved using micromachined silicon piezoresistive sensors because they are accurate, small, and cost effective. A variety of medical devices have been developed utilizing piezoresistive sensor technology to monitor intracranial [140], arterial [141], urethral [142], and gastrointestinal [143] physiologic pressures.

Existing technology to monitor intra-abdominal pressure are either sensor-tipped catheters or fluid-coupled transducers. Sensor-tipped catheters contain the sensor at the end of the catheter to be placed at the physiologic site of interest, which has been found to be more accurate than fluid-coupled transducers [22]. Sensor-tipped catheters require measurements in a fluid filled environment, such as the bladder or urethra, to achieve reliable pressure measurements. However, measurements in the bladder require proper catheter positioning and a controlled bladder fluid volume. In a nonfluid-filled space, such as the vagina or the rectum, the location and orientation of the sensor-tipped catheter can drastically change the pressure readings [23], [142].

Fluid coupled transducers utilize noncompressible fluids, such as saline, to transmit pressure from a physiologic site to an externally located sensor. These systems use inflated balloons to monitor pressure in a nonfluid-filled space such as the vagina or rectum. The length of the fluid filled tubing that conveys the pressure signal can have a substantial effect on the measurement accuracy [26], [27]. Damping and resonance

effects in these systems are dependent on component characteristics such as length, diameter, and stiffness of the tubing connecting the sensor with the site of measurement. Other factors such as air bubbles in the line can cause erroneous pressure measurements [25]. Nonetheless, this technique offers a solution for monitoring IAP during static conditions that exist under standard urodynamic laboratory testing. However, care must be taken to interpret the data and understand the limitations of these systems due to poor dynamic response during rapid changes in pressure [30].

Rectal balloon catheters are routinely used to indirectly monitor IAP during urodynamic and cystometry testing to determine urinary leak point pressures. During urodynamic and cystometry testing, a rectal balloon catheter is inserted >10 cm into the rectum filled with 5 ml of sterile saline solution. The cystometry machine is zeroed to atmosphere and connected to the rectal catheter [144], [145]. Once the rectal balloon catheter is linked to the cystometry machine, the height of the external transducer is adjusted to achieve an accurate reading [146]. Using this setup, along with a catheter that fills the bladder to a specified volume, leak point pressures are recorded during sitting Valsalva and cough as well as standing Valsalva and cough [146].

Activity studies conducted in 2006 and 2007 measuring indirect IAP in women during various activities suggest that common activity restrictions do not correlate well with measured IAP. In 2004 Weir et al. measured IAP using a microtip rectal catheter in 30 women and found that certain activities such as lifting 20 lbs produced no more increase in IAP than activities such as walking [8]. In the same study, activities such as abdominal crunches, climbing stairs, and walking at 3 mph showed little increase in IAP

levels compared to simply rising from a chair [8]. In 2008, Guttormson et al. published a similar study in which the IAP was measured in nine subjects, both male and female, using a Foley catheter in the bladder. The results of the study showed that peak IAP were greatest with forceful coughing and the Valsalva maneuver, and rising from a seated position generated IAP similar to that when lifting 10 lbs from the floor or 20 lbs from a table [9]. Both of these studies were aimed at overturning postsurgical activity restrictions but were only able to monitor IAP in a laboratory setting where movement was hindered by limitations of the catheter-based systems used.

Current sensor technology allows for IAP monitoring during short exercise periods in clinic or laboratory settings. Measurements of IAP in nonclinical settings are needed to understand how exercise performed out of a laboratory environment relates with IAP. Extended monitoring would be the first step in investigating how exercise and activity of daily living correlates with the progression and development of PFDs. Device limitations as described above have many shortcomings including a complicated setup procedure, the device being tethered to acquisition hardware that limits mobility, poor dynamic response, and device use not being comfortable for users, all of which make it difficult to monitor IAP out of a laboratory environment.

2.9 Proof of Principle Intravaginal Transducer (IVT)

To overcome the shortcomings of current devices, a proof-of-principle intravaginal transducer (IVT) was developed in 2009 by Johnson et al. [30]. The prototype combined design characteristics of sensor-tipped catheters, which monitor pressure at

the physiologic site, to that of the rectal balloon catheter with the ability to measure pressure in a nonfluid-filled cavity. The device consisted of a silicone elastomer bullet-shaped outer capsule with integrated electronic components mounted on a custom printed circuit board (PCB). The PCB components included a pressure sensor die, resistor, and a signal amplifier. The PCB was sealed in the elastomeric capsule and filled with deionized water, which acted as the transduction medium, coupling external forces to the sensor die. Calibration was performed and devices were tested in a controlled lab environment using a reference transducer and the clinical "gold standard" rectal balloon catheter with external transducer. The results demonstrated an increased dynamic response of the IVT in comparison to the rectal catheter. In vivo testing in the urodynamics laboratory showed accurate tracking of IAP using the 1st generation IVT with minimal pressure overshoot compared to the rectal transducer during rapid changes in IAP [30].

The proof-of-principle tethered IVT device demonstrated that IAP can be accurately monitored using a sensor at the site of physiologic measurement. After input from clinicians and patients, further modifications were needed to improve the reliability, durability, and portability of the device. To address reliability and durability concerns, it was hypothesized that gel could replace saline in transferring the pressure from external forces of the capsule to the sensor die. Bench testing validated the integration of the silicone gel by subjecting the prototypes to swept sine wave tests, impulse tests, temperature coefficient of offset, and sensitivity tracking (see Appendix A for results) [147].

In order to monitor IAP in real world settings, a mobile IAP pressure sensor is needed. The new device combines design characteristics of the proof-of-principle device along with that of the gel-filled first generation IVT. The next generation wireless IVT and base station will be designed and packaged in a manor to allow for IAP monitoring out of the laboratory in order to explore the relationship of IAP and exercise. Once a working wireless IVT is developed, the wireless IVT will be used to formulate a low intra-abdominal pressure exercise routine that can aide women in becoming physically active during postsurgical recovery.

2.10 Overview and Contributions

This line of investigation focuses on the development and use of the wireless remote abdominal pressure system (WRAPS) to monitor IAP during daily tasks and physical activity. This research is a part of a larger research project to monitor IAP in exercise and activities of daily living to revise postsurgical guidelines. During the development of the wireless intravaginal pressure sensor, the author collaborated with electrical engineers to develop circuit board design and determine supporting electronics needed and with software engineers to program electronics. Additionally, the author collaborated with exercise physiologists at the University of Utah that designed two exercise studies that are not explicitly presented in this dissertation, but highlight collaborative work that monitors IAP during exercise (see Appendix C and D). The author also collaborated with clinicians in the department of Obstetrics and Gynecology at the University of Utah to assist in developing the needs design of the wireless intravaginal

transducer and clinical evaluation in the Urodynamic setting (see Appendix B).

Chapter 3 is comprised of a peer-reviewed publication. Scientific contributions presented in Chapter 3 include 1) electronic package design, 2) using a commercially available wireless chip for deep tissue wireless communication, and 3) the package of a wireless pressure sensor to allow for accurate pressure monitoring with improved dynamic response over the clinical standard. The electronic package design incorporates two PCB and a coin cell battery, which provides power and structural support to the electronics package. The Zarlink wireless chip used in this application was chosen for its low transmitting power (< 25 μW) on the Medical Implant Communication Service (MICS) band and its established use in the medical field including the use in subcutaneous pacemakers. The Zarlink wireless chips were not developed for deep tissue applications such as monitoring intra-abdominal pressure in the pelvic cavity. To allow the use of the wireless chip, the electronic design presented in Chapter 3 incorporated a coaxial cable with external loop antenna to achieve reliable communication. Additionally, an elastomeric capsule was designed to house the electronic package and silicone gel to accurately monitor pressure and outperform the clinical standard rectal balloon catheter during dynamic testing. In Chapter 3, Tanner Coleman, Yvonne Hsu, Ingrid Nygaard, and Robert Hitchcock were responsible for conception and design of the primary device. Jens Thomsen was responsible for programming the device, while Tanner Coleman and Sean Maass were responsible for device assembly, experimental design, and data analysis. Tanner Coleman primarily wrote the manuscript. Robert Hitchcock and Sean Maass assisted in writing and provided review of the paper. All authors approved the final

version of the manuscript.

Chapters 4 and 5 are comprised of papers nearing submission to scientific journals. Chapter 4 contains major contributions including 1) common sensor faults and errors are measurable and can mostly be compensated, 2) certain errors such as drift must be considered for longer term studies, and 3) the device performance of the portable base station is similar to the application development kit base station and sufficient for out of clinic monitoring. In Chapter 4, Tanner Coleman, Kyle Hansen, Sean Maass, John Raynes, and Robert Hitchcock were responsible for study design. Tanner Coleman and Kyle Hansen were responsible for experimental setup, data collection, and data analysis. Tanner Coleman wrote the manuscript. Kyle Hansen, Sean Maass, and Robert Hitchcock assisted in writing and provided editorial review.

Major contributions of the exercise study presented in Chapter 5 include 1) the characterization of IAP during 22 Pilates Mat and Reformer exercises, 2) establishment of a sit-to-stand threshold activity of which all Pilates exercises are compared in order to establish exercise severity, 3) Introduction of a 40 cm H_2O threshold for calculating AUC which allows comparisons of activity area under the curve severity, and 4) the design of a low intra-abdominal Pilates exercise routine that could aide women during postsurgical recovery of pelvic floor surgery. In Chapter 5, Tanner Coleman, Dannielle Holder, Ingrid Nygaard, and Robert Hitchcock were responsible for study design. Tanner Coleman and Danielle Holder recruited participants for the study and designed the study protocol. Tanner Coleman was responsible for data collection, data analysis, and statistical analysis. Marlene Egger assisted in statistical analysis. Tanner Coleman wrote the manuscript and

was assisted by Dannielle Holder, Marlene Egger, and Robert Hitchcock with manuscript review.

2.11 References

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CHAPTER 3

DEVELOPMENT OF A WIRELESS INTRA-VAGINAL TRANSDUCER FOR MONITORING INTRA-ABDOMINAL PRESSURE IN WOMEN

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Development of a wireless intra-vaginal transducer for monitoring intra-abdominal pressure in women

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Abstract Pelvic floor disorders (PFD) affect one of every four women in the United States. Elevated intra-abdominal pressure (IAP) during daily activity or strenuous physical activity has been identified as a risk factor in the prevalence of PFD. However, the relationship between IAP and physical activity is poorly understood and oftentimes activity restrictions are prescribed by physicians without clinical evidence linking various activities to elevated IAP. There are currently no pressure transducers capable of monitoring IAP non-invasively out of a clinical environment. To overcome this shortcoming, a novel intra-vaginal pressure transducer (IVT) was developed to continuously monitor IAP. Improvements were made to the first generation IVT by incorporating wireless capability to enhance the device's mobility while creating a more robust IAP monitoring system. To ensure the changes maintained the functionality of the original device design, comparison testing with standard clinical pressure transducers in both bench top and clinical settings was conducted. The wireless device was found to have high linearity, robust signal transmission, and dynamic response that outperforms the clinical standard rectal transducer and is similar to the original first generation non-wireless design. The wireless IVT presented here is a mobile wireless device capable of measuring, storing and transmitting IAP data during various physical activities.

Keywords Pressure transducer · Pressure sensor · Intra-abdominal pressure · Vaginal transducer · Frequency response · Dynamic response · Physical activity

Abbreviations

IAP	Intra-abdominal pressure
PFD	Pelvic floor disorders
IVT	Intravaginal transducer
WRAPS	Wireless remote abdominal pressure system

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1 Introduction

According to a 2005–2006 National Center for Health study, nearly 24% of U.S. women are affected with a primary or recurrent pelvic floor disorder (PFD). Female pelvic floor disorders have been referred to as a hidden epidemic by clinicians in the United States (Hendrix et al. 2002; Nygaard et al. 2008). They often result from a weakening of the pelvic floor muscles and cause lifestyle altering symptoms such as incontinence and pelvic organ prolapse in which women experience herniation of the pelvic viscera such as the bladder, uterus and rectum into the vaginal cavity. The pathophysiology of PFD is unclear. One proposed disease mechanism, which lacks clinical support, is the increased load to the pelvic floor in the form of elevated intra-abdominal pressure (IAP) during physical activity. This lack of clinical understanding motivates the

need to investigate the role that elevated IAP plays in the progression, recurrence and incidence of PFDs during exercise and activities of daily living.

Physiologic pressure measurement systems typically employ electromechanical transducers that convert pressure into an electrical signal that can be processed, displayed and stored. Historically, devices that have been used to develop clinical standards for such measurements utilize micromachined silicon piezoresistive sensors which have high accuracy, small size and low cost. A variety of medical devices have been developed utilizing piezoresistive sensor technology to monitor intracranial (Minns 1984), arterial (Kinefuchi et al. 1994), urethral (Perucchini et al. 2002), and gastrointestinal (Fang et al. 2004) physiologic pressures.

Transducers based on microelectromechanical systems (MEMS) for physiologic pressure monitoring are used in conjunction with wireless telemetry techniques to transfer pressure data taken within the body to an externally located receiver (Tan et al. 2009). Telemetry systems are available from several manufacturers for both clinical and research use. One commonly available wireless system consists of an implanted sensor and external receiver in which internal power provides high data bandwidth at ranges of 0.2–5 m (www.datasci.com). This wireless scheme requires internal batteries which need to be recharged or replaced and oftentimes contribute to a larger implant size. Other wireless strategies utilize a passive telemetry approach for power and data transfer. These systems employ electromagnetic coupling and utilize backscatter amplitude modulation to detect signal changes (DeHennis and Wise 2005). Passive telemetry systems oftentimes have a smaller footprint and have increased implanted lifetime due to inductive power coupling. Other systems based on passive telemetry systems use coupled inductors where the sensor is passively powered by the receiver. In this system, the sensor oscillates as a function of pressure altering the frequency of the transmitted signal (Fonseca et al. 2006). Passive telemetry systems are approved by the FDA for use in endovascular monitoring (www.medscape.com). To date the fully implantable pressure sensors have only been developed for monitoring pressure in a fluid filled environment such as in vascular applications and are not suitable for measurements in body cavities such as the vagina or rectum.

Historically, intra-abdominal pressure measurement devices are classified as sensor-tipped catheters or fluid-coupled transducers. Sensor-tipped catheters are designed to place the sensor, located at the catheter tip, directly at the physiologic site of interest. Although, sensor tipped catheters are more accurate than fluid-coupled transducers (Stoker 2004), they require a fluid filled environment, such as the bladder or urethra, to achieve adequate and reliable pressure measurements. In a non-fluid filled space, such as the vagina or the rectum, the location and orientation of the sensor-tipped catheter can drastically alter the pressure readings (Holt et al. 1990; Perucchini et al. 2002). To overcome this shortcoming, sensor-tipped catheter systems are typically employed in the bladder but bladder fluid volume must be tightly controlled making IAP monitoring during daily activity impractical (Malbrain 2004).

Fluid coupled transducers utilize non-compressible fluids, such as saline, to transmit pressure from the physiologic site of measurement to an externally located sensor. These systems typically deploy inflated balloons which allow pressure measurements to be made in non-fluid filled environments such as the vagina or rectum. Due to the distance of the sensor from the pressure source, the fluid filled tubing that conveys the pressure signal can have a substantial effect on the measurement accuracy (Hunziker 1987; Hundley et al. 2006). Additionally, damping and resonance effects of these systems are dependent on component characteristics such as the length, diameter and stiffness of the tubing connecting the sensor to the site of measurement (Stoker 2004). Other factors such as air bubbles in the line can cause erroneous pressure measurements (Malbrain 2009). Nonetheless, this technique is preferable for measuring IAP during static conditions such as under standard urodynamic laboratory testing. However, care must be taken to interpret the data and understand the limitations of these systems due to poor dynamic response during rapid changes in pressure (Johnson et al. 2009).

The inadequacies of current pressure transducers have hampered our understanding of the relationship between IAP during activities of daily living and pelvic floor disorders. To overcome these shortcomings, our lab developed a proof-of-principle intravaginal transducer (IVT) that measured IAP using a piezoresistive sensor at the site of physiological measurement. The generation 1 device (Gen1) consisted of a silicone elastomer bullet-shaped outer capsule with integrated electronic components mounted on a custom printed circuit board (PCB). The PCB electronic components included a pressure sensor die, resistor and a signal amplifier sealed in the elastomeric capsule. Prior to use, the capsule was filled with sterile water which served as the transduction medium to couple the sensor die to external forces applied to the capsule. Bench top testing and preliminary human trials demonstrated that the Gen1 device had improved performance over the "gold standard" rectal balloon transducer in its ability to accurately measure rapid changes in pressure needed for real-world IAP measurements (Johnson et al. 2009).

The goal of the project described in this paper was to design a second generation (Gen2) IVT pressure sensor capable of wirelessly monitoring IAP during daily activity. The first generation proof-of-principle IVT was designed to

address many user needs such as user comfort, retention and accurate IAP monitoring (Johnson 2009; Rosenbluth et al. 2010). The Gen1 device however did not allow user mobility, lacked on-board calibration and required filling with water prior to use. Design modifications to the first generation devices were incorporated to address these problems while maintaining retention and comfort. The incorporation of the wireless technology required that pressure measurements be accurately recorded, stored and transmitted to the base station receiver. In addition, the wireless device needed to be comfortable to wear, retained during physical activities and easily removable. Here we report on the design, bench testing and preliminary *in vivo* evaluation of the wireless second generation IVT. This new design will allow for accurate intra-abdominal pressure measurements during routine daily activities outside of a clinical setting.

2 Materials and methods

The design strategy of the Gen2 device was to incorporate a microsensor, signal conditioner, microcontroller, power supply, and supporting wireless components into a gel filled elastomeric capsule. Wireless technology requirements were specified by the FCC Medical Device Radio communications Service (MedRadio). User safety, comfort, retention, and accuracy of intra-abdominal pressure measurement guided additional design requirements.

2.1 Capsule design

The analog Gen1 IVT was packaged in the Rev1 capsule that was modeled after female hygienic devices and consisted of a cylindrical elastomeric capsule measuring 27.4 mm in length, 12.7 mm in diameter and ending in a rounded terminus. To incorporate proposed wireless components while preserving retention and performance characteristics, modifications to the original capsule design were needed. The final capsule design (Rev4) consisted of a large diameter base of 23.9 mm tapering to 14.7 mm diameter at the distal terminus with an overall length of 37.3 mm. Capsules were injection molded using machined aluminum molds with silicone elastomer (MED-4940, Nusil) cured at 150°C for 5 min.

2.2 Microsensor package design and assembly

Space limitations of the capsule and size of electronic components required the electronic circuitry be separated into two electronic circuit boards. The insertable medical device (IMD) board side A (Fig. 1(a)) consisted of a pressure sensor (gauge-type microsensor—3SC 2000 IT, Merit Sensor Systems), signal processor (ZMD31014GID1, ZMD International Inc.) and four large solderable pads for attachment of the brass battery contacts. The battery contacts supplied power and ground from the coin cell battery while providing structural support to the electronics package. IMD side B (Fig. 1(b)) consisted of a MSP430 series microcontroller (MSP430F2132TRHBT, Texas Instruments) with 512 B onboard RAM for data buffering. Additionally, side B contained eight connection pads that served as the communication link between the IMD board and RF board through eight 34 gauge magnet wires (34 MAG, All Spectrum Electronics).

The radio frequency (RF) board side A (Fig. 1(c)) consisted of eight connection pads for communication with the IMD board and a Zarlink wireless chip (ZL70101LGD1, Zarlink). Wireless communication was achieved by utilizing the ISM radio band 402–405 MHz channel that is allocated for medical device communication by the FCC (wireless.fcc.gov). Side B of the RF board (Fig. 1(d)) consisted of matching RF network, antenna, and four connection pads for temporary attachment of communication wires for programming and calibration. As with the IMD board, power to the RF board was supplied through four brass contacts from the battery.

A piezoresistive pressure die was secured to the prepopulated IMD electronics board with a small amount of UV-cure adhesive (3311, Loctite) to one corner of the die. The sensor die was microbonded to the IMD board mating pads using a manual wirebonder (West Bond 7476D-79) with aluminum 1% silicon 75 μm diameter bonding wire (CFW0014026, California Fine Wire). The sensor die and bonded wires were sealed and reinforced using a small amount of UV-cure alkoxy silicone (5248, Loctite).

The battery holder provides a structural frame that secures the IMD, battery, and RF circuit board into an electronics package able to fit within the capsule. An assembly drawing of the electronics package is shown in Fig. 2. A knife plotter (Cutting Pro FC7000-75, Graphtec) was programmed to cut out an array of battery protectors from a 0.010″ polyester sheet as designed in a 2D computer-aided design CAD program (AutoCAD 2010, Autodesk). Each battery protector was separated from the sheet, folded around a 16 mm diameter aluminum rod and secured using UV-cure adhesive (3311, Loctite). Battery contacts were measured and cut from .006 in. thick brass shim stock. A short circuit protector was made using .002 in. polyester along with a knife plotter and CAD software. Once cut, the short protector was placed over the negative terminal of the coin cell battery (CR1632, Panasonic) preventing the brass shim stock from simultaneously contacting both the positive and negative terminals. A contact protector was designed to prevent electronic components on the circuit boards from contacting the

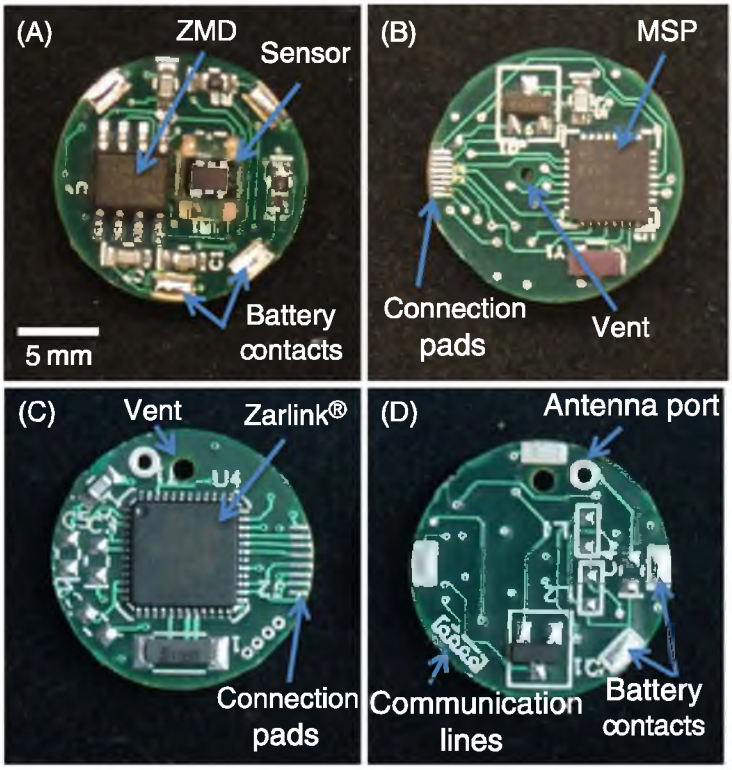

Fig. 1 Photograph of circuit boards and main features for wireless Gen2 circuitry. The IMD side A (**A**) contains the piezoresistive pressure sensor, ZMD signal processor and battery contacts. IMD side B (**B**) contains the MSP430 microcontroller and eight connection pads for linking the IMD board to the RF board. RF side A (**C**) contains the Zarlink wireless chip and connection pads. RF side B (**D**) contains four communication lines for programming and calibration and battery contacts

battery and was made using .010″ thick polyester sheet. Battery contacts were threaded though the precut slits of the battery protector securing the battery in the holder. The battery contacts were bent to accommodate both RF and IMD circuit boards in subsequent assembly steps. Contact protectors were placed at each end covering the brass contacts at both ends. Clear polyester shrink tubing .002″ thick (789200CST, Advanced Polymers) was cut to length and placed around the battery protector, heated, and secured in place around the outside of the battery holder.

A vent tube 0.027″ outside diameter 0.001″ wall thickness (Polyimide, Small Parts) was cut to length and threaded through the vent hole on the circuit board along with 0.2″ of exposed strain relief filament from the tether. UV-cure adhesive (3311, Loctite) was used to secure both the vent tube and strain relief to RF circuit board. The vent tube was then threaded through the hollow portion of the strain relief tether. The tether consisted of an extruded silicone elastomer with incorporated nylon filament. A coaxial cable (SMA RG-178, Digikey) was soldered to the RF electronics board. A patch antenna (ZLE70101BADA, Zarlink) was then attached to the coaxial cable prior to use.

Circuit boards were prepopulated on both sides with all components including the microbonded sensor die. Solderable magnet wire (34 AWG, All Spectrum Electronics) was cut to length and soldered into via holes on the IMD circuit

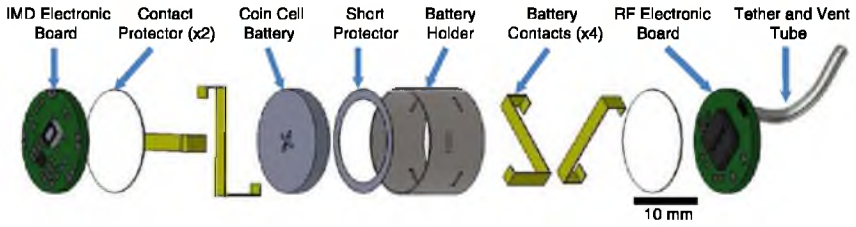

Fig. 2 Assembly drawing of electronic package. The battery is held in place by the four battery contacts. The contact protector at each end prevents the battery contacts from interfering with the IMD and RF circuit boards. Absent from this drawing are the shrink tubing, coaxial cable, and interboard communication wires

board side B. The magnet wire was threaded through the side wall between the battery and the battery protector and soldered to the corresponding pads on the RF circuit board side A. The battery contacts were folded making contact with the power pads located on IMD board side A and RF board side B and soldered. Once assembly of the electronics package was complete, four 32 gauge wires (32 AWG flex wire, Daburn) were soldered onto the programming pads on the RF board.

2.3 Final transducer assembly

Wireless devices were assembled by first pre-filling elastomeric capsules with silicone gel (MED6350, Nusil) and degassing the gel in a vacuum at −22 inHg. The IMD board side A and RF board side B PCBs were primed using a silicone primer (MED1-161, Nusil) and dried for 30 min at room temperature to improve the adhesion of the silicone gel and elastomer. The electronics package was then pressed into the capsule until no air bubbles were observed. The silicone gel and electronic package was cured in place at 70°C for 30 min. Silicone elastomer was used to pot the end of the capsule using an injection mold system. The devices were then allowed to cure at 150°C for 10 min. A cross-sectional view of the completed sensor design (absent elastomer potting and patch antenna) is shown in Fig. 3.

2.4 Wireless prototype bench testing

Programming and calibration of wireless Gen2 IVT prototypes was achieved through a four-wire JTAG connection using an interface board, MSP430 debugger (MSP-FETU430IF, Texas Instruments) and a computer. The IVT was sealed in a pressure chamber allowing the vent tube to be exposed to atmospheric pressures. Sensor output of three parameters: atmospheric offset, gain, and temperature coefficient of offset (TCO) were needed for calibration. To obtain the atmospheric offset counts, the ZMD signal processor averaged pressure counts of the Wheatstone bridge for 5 s at a frequency of 30 Hz. Next, gain was obtained by pressurizing the vessel to 5 psi (350 cm H_2O) using a NIST traceable reference transducer (Testcom, ER3000) at room temperature and averaging the pressure counts for 5 s at 30 Hz. The TCO was calculated by calibrating the ZMD internal thermistor at room temperature and at 37°C at atmospheric pressure. The offset of the sensor was normalized by setting 0 psi to 8,192 counts and gain set to 16,383 counts at 5 psi (350 cm H_2O).

A pressure chamber was built to test the impulse and frequency response of the wireless Gen2 IVT as shown in Fig. 4. The vessel consisted of a clear PVC pipe (2 3/4″ OD×2 1/2″ ID×6″, US Plastics) sealed to a PVC threaded cap (PVC 2″ threaded cap, US Plastics) and adaptor (PVC 2″ male adapter, US Plastics) with plastic adhesive (Scotch-Grip 4475, 3 M). A multifunction pressure waveform generator (WGA-200, Millar Instruments) was connected to an electromagnetic pressure converter (Millar Instruments) mounted atop the airtight compartment. The pressure waveform was controlled by a function generator (33220A, Agilent Technologies). A conventional blood pressure transducer (Intran, Utah Medical) was modified to expose the gel-filled pressure aperture directly to the water in the chamber. The blood pressure transducer, Gen2 IVT and rectal balloon catheter (CAT509, Laborie Medical) were all threaded through a hole in three stopcocks and sealed in designated holes in the threaded cap. The rectal balloon catheter was filled with deionized water until air bubbles were eliminated and was subsequently connected to a second blood pressure transducer. The testing vessel was filled with deionized water. Using the function generator, a swept sine wave and impulse (square wave) tests were performed to analyze the dynamic response of the transducers according to industry guidelines (ANSI/AAMI 1994/(R)2006). Reference and rectal balloon trans-

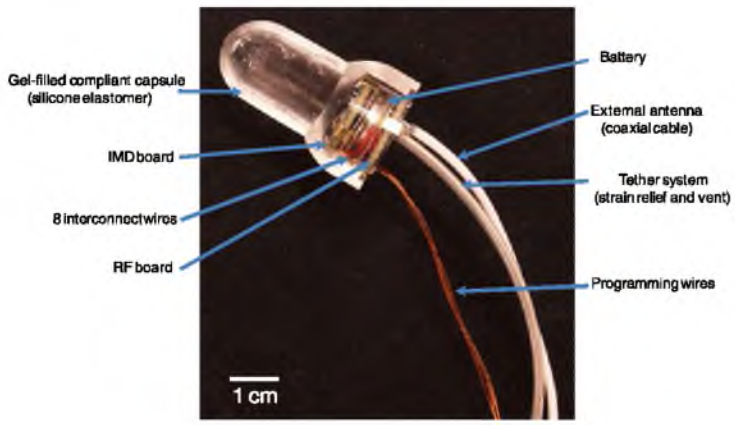

Fig. 3 Photograph displaying a cross section of the wireless intravaginal transducer. A coin cell battery is sandwiched between the IMD and RF circuit boards. The clear battery holder houses the electronics and battery in place supported by brass battery contacts. Four programming wires allow for programing and calibration. These wires are removed after calibration and prior to final device assembly. The tether is used for device retrieval and serves as an atmospheric vent. An coaxial cable allows attachment of an external antenna

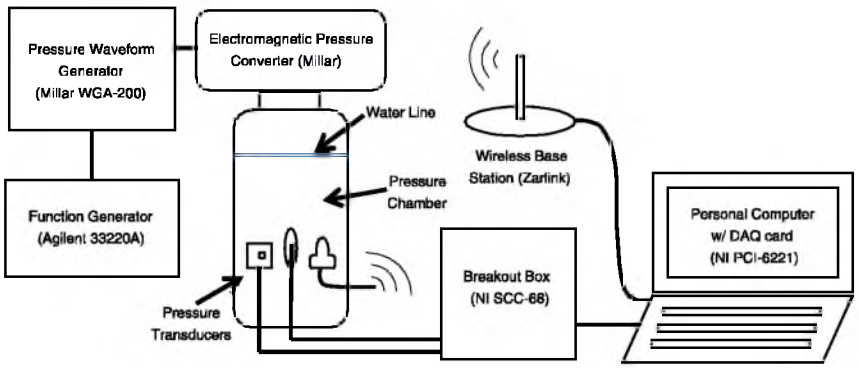

Fig. 4 Dynamic response test setup. All three pressure transducers were sealed in the pressure chamber. (from *left* to *right*: reference transducer, rectal balloon catheter and wireless Gen2 IVT)

ducer outputs were recorded at 1,000 Hz and stored using a breakout box (SCC-68, National Instruments), a DAQ card (PCI-6221, National Instruments), and a custom LabView 8.0 program. Measurements were converted from voltage to pressures using the calibration transfer function and filtered with a 10-sample moving average. Wireless Gen2 IVT outputs were recorded at 30 Hz and stored using a Zarlink ADK base station and computer.

2.5 Wireless prototype clinical testing

After obtaining study approval from the University of Utah Health Sciences Center Institutional Review Board, informed consent was collected from seven volunteers undergoing standard urodynamic testing. A sterile wireless Gen2 IVT and standard rectal balloon catheter was placed in each study participant by a member of the clinical research team. Each participant performed a series of coughs followed by a Valsalva maneuver both in the seated and standing position. Rectal balloon IAP readings were recorded at 15 Hz using clinical cystometry software (Laborie Medical Technologies) under a standard bladder volume of 200 ml. Wireless IVT pressure measurements were taken at 30 Hz using the Zarlink ADK base station and custom laptop software. Results of each transducer were plotted and compared.

3 Results

3.1 Wireless prototype bench testing

The gel-filled wireless GEN II IVT was calibrated using the ZMD signal conditioner to have an average count of 8,192 at 0 cm H_2O and 16,383 counts at 350 cm H_2O.The calibrated sensor demonstrated a highly linear response (R^2=1.0000) from 0 to 350 cm H_2O and a sensitivity of 23.44 counts/cm H_2O (Fig. 5). The dynamic performance of the gel-filled IVT is shown by the impulse response test shown in Fig. 6. The fluid-coupled rectal balloon catheter exhibited a response typical of an underdamped second-order system. An overshoot of 35% was measured from the balloon catheter's response to an impulse pressure input. An overshoot of 2% was measured during the same test from the Gen2 IVT. The swept sine wave test results (Fig. 7) show a resonant frequency with the rectal balloon catheter but not with the reference transducer or Gen2 IVT. The natural frequency, F_n, of the rectal balloon catheter was calculated to be 24.6 Hz and the damping coefficient, D, was calculated to be 0.30 exemplifying a highly underdamped system (AAMI 1992). The flat bandwidth (15% tolerance) of the balloon catheter was determined to be 15 Hz from the swept sine wave results. Flat bandwidth is defined as the range of frequencies starting at 0 Hz at which accurate measurements are obtained (AAMI 1994). Natural frequencies and damping coefficients for the Gen2 IVT were incalculable with no measured overshoot in swept sine wave tests.

3.2 Wireless IVT clinical evaluation

Wireless Gen2 devices capsules were tested against a conventional urodynamics balloon catheter placed in the rectum. Pressure measurements made by the wireless Gen2

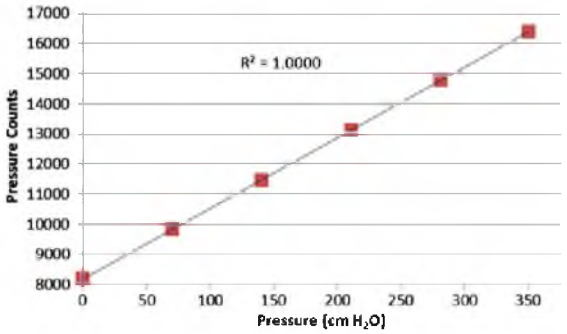

Fig. 5 Calibration curve for wireless Gen2 IVT

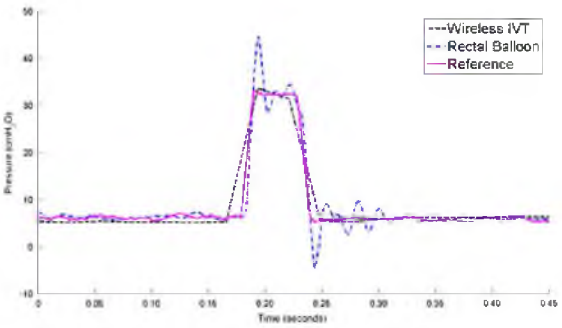

Fig. 6 Results of three transducers during an impulse response test

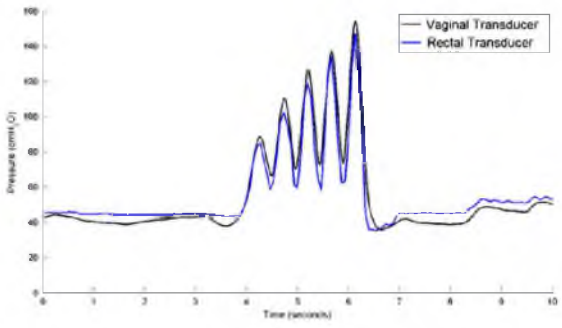

Fig. 8 IAP measurement while subject coughs 4 times

IVT were consistent with rectal catheter data in both coughs (Fig. 8) and Valsalva maneuvers (Fig. 9).

4 Discussion

The Gen2 IVT is a significant step towards our goal of developing a device to continuously monitor IAP during daily activity. The improvements made to the first generation IVT include the integration of a silicone gel, onboard calibration, and wireless technology. Modifications to the original design were tested against standard clinical devices to ensure device performance and data integrity. Wireless technology allows users free mobility while providing the clinician accurate IAP monitoring during daily activities. It is through this monitoring that clinicians can begin to study the relationship between intra-abdominal pressure (IAP) and the progression of pelvic floor disorders in a real world setting.

4.1 Capsule design and electronics package

Capsule size and shape was influenced by the size of electronic components, user retention, and device performance. The gel-filled portion of the elastomeric capsule acted as the transfer medium to couple external forces applied to the capsule to the sensor die.

The integration of a signal conditioner, microcontroller and wireless components allow the wireless Gen2 IVT to be calibrated, packaged, sterilized and stored prior to use. The ZMD uses a CMOS amplification and analog-to-digital conversion unit for bridge input signals. This analog-to-digital output converts output voltage from the sensor into pressure counts. Each count represents a specific pressure and is compensated for offset and the temperature coefficient of offset (TCO) using a built in thermistor and internal digital correction algorithm. The ZMD signal conditioner communicates with the MSP430 microcontroller through the I2C digital output pins allowing programming and calibration coefficients to be controlled exclusively through the MSP430. The MSP also serves as a temporary data storage unit for pressure counts which is cleared once a wireless session is established between the Gen2 IVT and the base station. The MSP includes 8 KB + 256 B flash memory with 512 B RAM storage capacity and is compatible with I2C communication and synchronous SPI protocol for communication with the Zarlink wireless chip.

The RF board consists of the Zarlink wireless chip and matching RF antenna network. Each wireless Gen2 IVT is

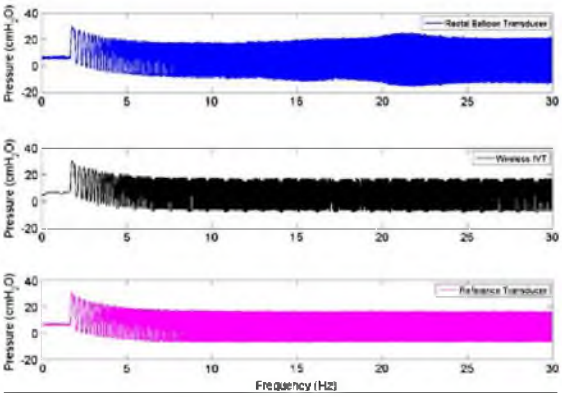

Fig. 7 Swept sine wave frequency plot for three transducers

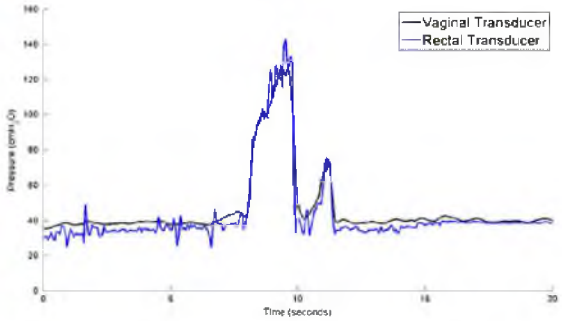

Fig. 9 IAP measurement while subject performs a Valsalva maneuver

flashed with a unique identifier that allows for device initialization by activation of the 2.54 GHz wakeup signal sent by the base station. The wakeup signal initializes the MSP and ZMD to wake-up out of low power mode to start data acquisition. As pressure measurements are recorded the MSP temporary memory will start to fill with pressure counts. Once a session is negotiated between the base station and the Zarlink wireless chip, a wireless data packet consisting of the pressure counts in the MSP buffer is sent to the base station utilizing the 400–404 MHz transmission band. The transfer of the wireless packet clears the buffer in the MSP allowing it to be refilled with pressure counts. Ideally, a wireless session between the base station and the Gen2 IVT will occur every 1.5 s sending one wireless packet consisting of 45 pressure counts. The wireless packet received by the base station contains header information that denotes device status, temperature and error messages followed by relative time stamps assigned to each pressure count.

4.2 Calibration and dynamic response

The ZMD signal conditioner converts output voltage of the sensor into pressure counts. Calibration of the Gen2 IVT eliminates offset of the sensor by adjusting the ZMD output to 8,192 counts at 0 cm H_2O. Temperature coefficient of offset is compensated allowing the ZMD to output 8,192 counts at 0 cm H_2O at a temperature of 37°C. The wireless Gen2 IVT is programmed to utilize half the ZMD resolution and outputs 16,383 counts at 350 cm H_2O or 23 counts/cm H_2O. If necessary the ZMD can be configured to utilize the full resolution of the device by setting the pressure counts to 0 at 0 cm H_2O and 16,383 counts at 350 cm H_2O or 47 counts/cm H_2O. The requirements of the IVT specified an accuracy of 1% of full range (full range = 350 cmH_2O) and therefore using half the headroom of the ZMD counts was sufficient for the performance of this device.

Comparing the dynamic response of the wireless IVT to the Utah Medical reference transducer showed no resonance effects during the swept sine test. The rectal balloon catheter accurately tracked pressure during gradual pressure changes (i.e. low dP/dt) less than 15 Hz when compared to the reference transducer. However, during abrupt pressure changes (i.e. high dP/dt) above 15 Hz, resonance effects were seen in which flat bandwidth tolerance is exceeded by the transducer. These results were further demonstrated during the impulse response test where the wireless IVT showed little overshoot while the rectal balloon catheter recorded a 35% overshoot in pressure when compared to the reference. These results are typical of an underdamped ($D < 1$) pressure measurement system where fluid inertia, tubing compliance and viscous effects contribute to the error during abrupt pressure changes (Stoker 2004). The sampling rate of the wireless IVT is optimally set at 30 Hz to adequately capture IAP changes during exercise while conserving battery life. The 30 Hz sampling rate resulted in aliasing effects in the wireless IVT during the swept sine wave test and impulse response test, both of which were not observed in the rectal balloon or reference transducers sampled at 1,000 Hz. Despite the aliasing effects, no resonance characteristics were observed during the wireless dynamic response test, a result that is supported by previous bench testing on analog devices (Coleman et al. 2010). Oscillations in pressure during baseline and swept sine wave tests were observed in the Gen2 IVT. These oscillations were between 1 and 2 cm H_2O in amplitude and occur at regular intervals of 1.5 s, corresponding to a wireless data packet transmission. These dips in pressure measurement are a result of a slight power drain in the electronic circuitry but are not observed to exceed the AAMI standard of 15% flat bandwidth tolerance (AAMI 1992). A downward drift in pressure was observed in all transducers in the frequency range of 0–5 Hz. This drift is attributed to an insufficient seal in the test vessel, initially forcing air out of the system during testing. At the conclusion of each test the baseline pressure returned to pre-test levels.

Drift of atmospheric pressure measurements have been observed during post calibration and post sterilization readings of the wireless IVT (data not shown). To combat the day to day drift in atmospheric baseline, sensor readings are taken prior to human use to establish the atmospheric baseline pressure reading. Subsequent data analysis corrects for the positive or negative offset change by referencing all subsequent pressure measurements to atmosphere. Further studies are needed to characterize drift over time.

4.3 Clinical measurement

Wireless Gen2 devices showed equivalent IAP tracking when compared to rectal balloon catheter *in-vivo*. True IAP pressures are obtained directly in the peritoneal cavity, a challenging and highly invasive measurement which is unreasonable for the purposes of our study. We chose to compare the wireless IVT response to the clinical standard IAP transducer, the rectal balloon catheter. During activities with gradual pressure changes such as Valsalva maneuvers and isolated coughs both transducers were found to be comparable. This study did not investigate exercise activities such as jumping or running, which exhibit rapid changes in IAP pressure, because study participants were clinical patients undergoing a standard urodynamic study. However, past urodynamic studies showed rapid changes in IAP, associated with jumping, resulted in pressure overshoot of the rectal balloon catheter that was not observed in the first generation IVT (Johnson 2009). Therefore, we

believe the IVT proves a more accurate account of IAP during rapid pressure changes useful in measurement of women undergoing a broad range of activities in a real-world setting. This conclusion is supported by the impulse and swept sine wave tests.

5 Conclusion

The results of this study demonstrate the ability of the wireless Gen2 IVT to accurately and reliably measure intra-abdominal pressure when compared to the reference and rectal balloon catheters. The improvements to the first generation design were validated using both bench top and clinical testing. The integration of an on-board signal conditioner allows the atmospheric and temperature offset to be compensated while applying the gain (sensitivity). Wireless technology allows the versatility of free movement within the laboratory setting while establishing the foundation for future development of the Wireless Remote Abdominal Pressure System (WRAPS). Future development will focus on creating an on-person base station receiver with micro SD memory storage allowing for continuous "real world" IAP tracking. Long term measurements during "real world" activities and exercise will provide researchers and clinicians with valuable information regarding the load profile on the pelvic floor and the correlation with the incidence, progression and reoccurrence of pelvic floor disorders.

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CHAPTER 4

CHARACTERIZATION OF A WIRELESS REMOTE ABDOMINAL PRESSURE SYSTEM

4.1 Abstract

Intra-abdominal pressure is thought to play a role in the incidence, progression, and reoccurrence of pelvic floor disorders in women. Until recently, there was no convenient method of measuring intra-abdominal pressure outside a clinical environment. To address this need, we have developed a wireless remote intravaginal transducer system for tracking intra-abdominal pressure. Design verification testing was conducted on 10 wireless pressure transducers to characterize the performance of the sensor for linearity, drift, temperature coefficient of offset, change in sensitivity, and offset due to orientation. Additionally, verification testing was performed on the newly created portable base station including pressure acquisition frequency and wireless power output. Five portable base stations, used to collect and store pressure readings from the wireless intravaginal transducers, were evaluated to verify the data capture rate and the wireless power output of the system. The transducer deviation from linearity was found to be less than 1% for all sensors, temperature coefficient of offset averaged 0.54 cm H_2O/°C, offset was changed by 2 cm H_2O from upright to inverted position, and drift

over 1.5 hours averaged -0.81 cm H_2O. The portable base station and wireless intravaginal transducer had an average acquisition rate of 31.2 Hz. The power output of the portable base station was found to be 7.6 and 14.1 dBm lower than the Zarlink application development kit system at 2.45 GHz and 400 MHz, respectively. Overall the wireless remote abdominal pressure system meets design specifications and accurately tracks and stores intra-abdominal pressure measurements in real world applications outside of the clinical environment.

4.2 Introduction

Pelvic floor disorders (PFDs) have been reported as a hidden epidemic in both the clinical research literature [1] and popular press [2]. PFDs include pelvic organ prolapse, urinary incontinence, and fecal incontinence. The number of women affected by a PFD in the United States averages 23% and ranges from 9.7% to 49.7% depending on age [3]. The risk factors for pelvic floor disorders are considered multifactorial [3]–[6]. One understudied factor that may lead to pelvic floor disorders is elevated intra-abdominal pressure (IAP). IAP directly affects the load on the pelvic floor and can change due to many factors including exercise and activities of daily living. Until recently there was no convenient method of measuring intra-abdominal pressure outside a clinical environment. We have reported previously on the development of a Wireless Remote Abdominal Pressure System (WRAPS) that allows for measurements of intra-abdominal pressure in real world situations outside of the clinic and is proving to be a unique analytical tool for better understanding the role that IAP plays in PFD [7], [8].

The WRAPS consists of two subsystems: a wireless intravaginal transducer (WIVT) and a base station. The WIVT assembly includes a piezoresistive pressure sensor, battery, signal conditioner, microcontroller, and wireless transceiver encapsulated in an elastomeric capsule filled with silicone gel. The base station can either be a custom designed portable base station, which uses the wireless Zarlink transceiver or the Zarlink application development kit (ADK) base station. Intra-abdominal pressure is measured via the WIVT and sent wirelessly to the portable base station located on the user or to the ADK base station connected to a laptop. The WIVT builds upon principles of established microelectromechanical systems combining the accuracy of sensor-tipped transducers to measure pressure at the physiologic site with the ability to measure pressure in a nonfluid-filled cavity [7], [9], [10].

4.2.1 Sensor Packaging

Various pressure transducer systems are used to monitor physiologic pressures including blood [11], intrauterine [12], and intracranial pressures [13]. Blood pressure can be measured directly by placing a transducer in the vascular system or indirectly by coupling an external transducer via fluid filled tubing to an indwelling vascular catheter. Direct monitoring is preferred over indirect methods in order to better manage hemodynamically unstable ICU patients [14] and to detect blood flow difficulties or cardiovascular problems at an early stage [15].

Typical physiologic pressure transducers work by the deflection of a silicon pressure sensor membrane arranged in a gauge configuration in which the side exposed

to physiologic pressure is compared to a reference side that is vented to atmosphere. Electronic circuitry monitors the change in capacitance or resistance of the sensor during diaphragm deflection. The electronic signal is then converted into a pressure measurement using a calibration transfer function. Pressure transducers are packaged to minimize thermal expansion and contraction stresses while isolating the electrical portions of the device from the patient [16]. This is typically achieved by mounting a piezoresistive sensor on a thermally isolated substrate such as a ceramic board and encapsulating the sensor with a dielectric such as silicone gel. The encapsulation not only isolates the sensor electrically but also provides a transfer medium from physiologic pressure to the sensor.

4.2.2 Sensor Errors

Several types of errors can be found in all types of physiologic pressure transducers. The most common are 1) temperature errors, which alter the output of the sensor at any given pressure due to changes in temperature [10]; 2) offset errors, also known as baseline drift, which are defined as the change in sensor output at zero pressure [17], and 3) sensitivity errors, also known as gain errors, which occur when the slope of the pressure/output curve varies with time [10]. Most of these errors can be minimized through the careful design of the sensor, packaging, and electronics.

Temperature errors are changes in sensor output either through a change in offset or a change in sensitivity. These changes are characterized during testing and are defined as the thermal coefficient of offset (TCO) and thermal coefficient of sensitivity (TCS).

Temperature changes on an unpackaged piezoresistive sensor can lead to errors of up to 20% of the sensor output [18]. The packaging of a piezoresistive sensor adds additional temperature susceptibility including thermal expansion and contraction of the polymers surrounding the sensor, circuit board, and the sensor substrate. Therefore, pressure transducers must be packaged to isolate the pressure diaphragm and circuitry from thermal expansion and contraction so that supporting electronic circuitry will not expose the silicon sensor to mechanical stress [15]. Recent developments in low-cost signal conditioners have popularized their use in correcting temperature induced errors by applying compensation values to both offset voltage and span as well as to provide an appropriately amplified signal [19].

Offset errors can also occur at constant temperature and are a primary reason why physiologic pressure sensors are regularly rezeroed [20]. Many types of sensors are susceptible to isothermal offset errors which can be caused by many factors including system setup, orientation, calibration, and packaging. Offset errors can also manifest as a constant bias from incorrect pressure sensor calibration, resulting in data values that are offset from the true pressure by a constant amount [17]. As an example, a catheter based arterial pressure monitoring system is normally calibrated to read zero pressure when the sensor is exposed to atmosphere. However, if a transducer is zeroed while exposed to hydrostatic column of fluid, such as an inline medication delivery system, it will underread the true physiological pressure [20]. Proper setup is critical for sensor rezeroing.

A sensitivity error occurs when there is a change in the sensitivity—defined as

system output (e.g., voltage) with respect to the sensor input (e.g., pressure). As a result of drift error, the offset or gain may change over time [17].

Due to the variability of sensor packaging for various pressure measuring devices, the Association for the Advancement of Medical Instrumentation (AAMI) established a standard for blood pressure measurement, accuracy, and verification testing as outlined in the TIR:9 1992 and BP:22 1994 [21], [22].

Drift errors occur when a sensor's original calibration constants change during use [23]. This particular error makes it difficult to differentiate between miscalibration and physiologic pressure variations and results in a lower accuracy of sensor measurements but not necessarily lower precision [17]. Many pressure sensors have encountered difficulty in drift, and this has led to several recalls by the FDA [24]. Sensor errors are not limited to calibration errors and may have multiple contributing factors including power supply, temperature [20], mechanical, and electrical error types. For example a failing battery supply may cause sensor output to experience zero variation for an extended period of time [17].

Physiologic pressure monitoring is a routine part of modern clinical practice, and pressure transducers have been adapted and packaged specifically to meet the needs of each application. In our application we have developed a transducer that can directly and continuously measure pressure in the upper vagina. In order to evaluate proper performance, a series of tests were conducted to verify that assembled devices met the design requirements. Thus, this study aims to test the Wireless Remote Abdominal Pressure System (WRAPS) to provide additional evidence supporting our group's clinical

findings and further establish a performance baseline for future design modifications. Here we report on the linearity characteristics, long term atmospheric drift, dynamic force changes, and sensitivity changes of the WIVT and determine the performance characteristics of the portable base station. Adequate characterization of the WRAPS is pivotal for expanded testing outside of a laboratory environment where experimental factors cannot be tightly controlled and anticipated.

4.3 Methods

The WIVT is a pressure sensor designed to monitor intra-abdominal pressure in the upper vagina. The WIVT utilizes a piezoresistive pressure sensor that is sealed, along with supporting electronics, in a gel-filled elastomeric capsule. During data collection, an on-board radio transmitter in the WIVT transfers data packets containing stored pressure data to a base station transceiver. The electronic components and design specifications have been previously described [7].

During bench testing, the Zarlink application development kit (ADK) base station and a laptop computer was used to monitor WIVTs. The base station sends a wakeup signal on the 2.45 GHz industrial, scientific, and medical (ISM) band containing a unique identification (ID) number. All WIVT within range will wake up from a low power mode and reference the ID number. The WIVT with the correct ID will then enter active mode, where it is programmed to acquire pressure readings at 32 Hz (samples per second). Pressure readings are sent from the WIVT Zarlink wireless chip to the base station using the Medical Implant Communication Service (MICS) 402–405 MHz channel. Using this

system, data displays can be updated with each wireless packet that is received. Data are then plotted and interpreted using a custom Matlab (R2011A, MathWorks) program.

4.3.1 Wireless Intravaginal Transducer Testing

Ten WIVT sensors were calibrated for gain and atmospheric offset. To obtain the atmospheric offset, the signal processor averaged voltage of the Wheatstone bridge for 5 seconds at a frequency of 32.3 Hz at room temperature with the pressure vessel vented. These voltage values are reported in counts from the on-board signal processor (ZMD31014GID1, ZMD International Inc.). Next, gain was obtained by pressurizing a test vessel to 351.5 cm H_2O (34.5kPa) in increments of 70.3 cm H_2O (6.9kPa) using a NIST traceable reference transducer (Tescom, ER3000) and averaging counts at each iteration. The offset and gain of the sensor were normalized by setting 0 cm H_2O to 7809 counts and 351.5 cm H_2O to 16000 counts. After calibration, a sensitivity curve was generated to check the variation (Vn) from a linearity using (4.1), where n is one of six measurement points 0–351.5 cm H_2O, C is the count values, and S is the sensitivity in counts/cm H_2O. Two data points at 0 cm H_2O (C0) and 351.5 cm H_2O (34.5 kPa) (C5) were used to determine ideal linearity.

$$V_n = \frac{(C_n - C_0) - (\frac{(C_5 - C_0)(n-1)}{5})}{S \cdot 70.308} \tag{4.1}$$

After calibration, sensors were heated from room temperature (approximately 23.5 °C) to 37 °C. The sensors were monitored for 10 minutes at room temperature. The sensors were then submersed into a 0.90% w/v of NaCl saline solution that was preheated

to 37 °C using a water bath (Aquabath, Lab-Line), covering the entire elastomeric package for 10 minutes. The sensors were maintained in the same orientation during both test phases with an acquisition rate of 32.3 Hz. Temperature coefficient of offset (TCO) for each device was calculated by averaging pressure values between 2 and 7 minutes into the test, establishing an offset pressure at room temperature and again during the last 2 minutes of the test to determine the offset pressure at 37 °C.

The effect of orientation on sensor readings was tested. WIVT were wrapped in a low density polyurethane foam and lightly clamped in a buret clamp that was mounted on a lab stand. The clamping force was sufficient to hold the sensor but did not alter the output. Sensors were monitored at 32.5 Hz for 60 seconds during each orientation from upright (90°), horizontal (0°), and inverted (-90°). Mean and standard deviation of the pressure values were calculated.

To evaluate short term-sensor offset drift, 10 WIVT remained in a 37 °C bath of 0.90% w/v saline for 1.5 hours to simulate an in vivo environment. The sensors, reaching their thermal equilibrium during the TCO testing, were again monitored continuously at 32.3 Hz during the drift test. The 90 minutes of drift data were subdivided into nine segments, 10 minutes in length. The average drift rate for each segment was calculated by averaging each segment and subtracting the n+1 segment from the n^{th} segment for n = 1–8. The overall drift rate was calculated by subtracting the first segment from the last segment.

To understand the mechanical and calibration changes during in vivo use, five sensor pairs were manufactured in the same fabrication lot for testing purposes. For each

of the five pairs, one sensor was used to monitor intra-abdominal pressure using the portable base station during a 1.5-hour long exercise routine. After the exercise portion of the test, each sensor pair was placed back inside the calibration chamber and repressurized from 0–351.5 cm H_2O with a 15-second pressure recording at each increase of 70.3 cm H_2O. The obtained sensitivities were compared against original calibration values.

4.3.2 Portable Base Station Testing

A custom portable base station was developed for ambulatory testing. The base station performs wakeup and receiver functions similarly to the Zarlink ADK base station. The portable base station (Figure 4.1) contains a microcontroller (MSP430F1611IPM, Texas Instruments) and Zarlink Base Station Module chip (ZL70120, Microsemi) in addition to discrete components and a microSD card for data storage. All electronic components are powered by two AAA batteries (LR03XWA/B, Panasonic) in series. Two antennas are utilized, one for the 2.45 GHz wakeup signal (RN-SMA-S-RP, Microchip Technology) and the other for the 400 MHz receiver antenna (ANT-418-CW-RAH, Linx Technologies). The MSP430 microcontroller, which controls the Zarlink radio, stores wirelessly transmitted pressure values from the WIVT on the microSD card.

Prior to use, the microSD card must be preprogrammed with two files: an insertable medical device (IMD)-ID file, which contains the specific WIVT ID, and a real time clock file that is used to determine the relative time of each pressure measurement. The portable base station operation is shown in Figure 4.2. Once the portable base station

is turned on, the user must initiate wireless acquisition by pressing the base station function button. An indicator light is flashed with each wireless session to provide system status. A green light indicates that a wireless session is negotiated between the base station and IMD and a data packet is received. A red light indicates when a wireless connection failed to initialize and no data was transmitted.

Once the exercise is concluded the user will then press the button again to stop data acquisition, placing the base station in a standby mode. This cycle of acquisition and standby is used to record individual exercise activities during a long exercise protocol. After exercise is complete the base station is turned off and the microSD card is extracted. The microSD card contains a WRAPS.BIN file that is converted into a .YAML file and then to a .CSV to be analyzed. Each time the base station button was pressed during exercise, an event marker is placed in the .BIN file that allows for data analysis on a per activity basis.

The data capture rate of the portable base station was evaluated by monitoring five WIVTs for 5 minutes using both the Zarlink ADK base station and the portable base station. For each measurement the time stamp of the data point was subtracted from the previous time stamp to determine the interval between successive pressure measurements. Based upon the interval time between measurements, a data acquisition frequency was calculated for the Zarlink ADK and the portable base station.

A spectrum analyzer (N1996A, Agilent) was used to determine the power ratio of the 2.45 GHz wakeup signal and 400 MHz data signal between the portable base station and the Zarlink ADK base station. Either a 2.45 GHz 1" short antenna or a 418 MHz 1/4th

wave whip antenna was connected to the input port of the spectrum analyzer by a 50 ohm coax cable. Each base station was placed .91 m away from the input antenna and activated. The spectrum analyzer was programmed to capture both maximal peaks and 100 point average values during a 30-second period. Center frequency was compared between all devices.

4.4 Results

4.4.1 Wireless Intravaginal Transducer Bench Top Tests

The calculated R^2 value for the WIVT during device calibration was 1.0000. The deviation from linearity from a straight line curve is shown in Figure 4.3. The average deviation from linearity at 70.3 cm H_2O was 0.118 cm H_2O, 140.6 cm H_2O was 0.167 cm H_2O, 210.9 cm H_2O was 0.113 cm H_2O, and 281.2 cm H_2O was 0.093 cm H_2O.

Ten sensors were monitored at atmospheric pressure at an average room temperature of 23.5 °C for 10 minutes and then were heated in a water bath to 37.0 °C for 10 minutes. Figure 4.4 shows a typical result of the increasing temperature on the pressure counts during the test. Table 4.1 contains the average counts at 23.5 °C and 37.0 °C, the pressure increase, and the pressure increase per degree Celsius for each sensor.

Orientation testing showed a decrease in pressure from upright (90°) to side (0°) to inverted (-90°) position. This difference averaged 1.0 ± 0.8 cm H_2O (mean ± standard deviation) between the upright to side position and averaged 1.2 ± 0.7 cm H_2O from side to inverted positions.

The average drift over a 10 minute segment for all 10 sensors was found to be

-0.10 ± 0.05 cm H_2O (mean ± standard deviation) with a maximum drift of -0.21 cm H_2O. Drift over 1.5 hours was calculated by subtracting the last segment from the standard segment. The average drift over 1.5 hours with all 10 sensors was calculated to be -0.81 ± 0.36 cm H_2O with a maximum drift of -1.65 cm H_2O.

The average change in sensitivity per day given in counts/cm H_2O for the non-in vivo sensors was -0.004 ± 0.008 counts/cm H_2O·day, while the average percent change in sensors undergoing in vivo testing was -0.010 ± 0.008 counts/cm H_2O·day. A two sided t-test with equal variance was performed to determine the statistical difference of used and unused sensor which resulted in a p value of 0.306 at an alpha of .001. The change in sensitivity in regard to sensor pair, the number of days between initial calibration, and retesting sensitivity are shown in Table 4.2.

4.4.2 Portable Base Station Tests

The ADK base station monitoring the WIVT had an average acquisition of 31.1 Hz, while the portable base station monitoring the WIVT was found to have an average acquisition of 31.16 Hz (Table 4.3). Periods in which the WIVT buffer was overrun and data were lost were eliminated from analysis as the time to reestablish communication between devices is highly variable. Wireless data loss occurred between 1–5 times over 5 minutes. Time periods between measurements ranged from 0.031 seconds to 0.095 seconds with the majority of the time periods occurring at 0.031, 0.049, or 0.080 seconds.

The Zarlink ADK base station power of the 2.45 GHz wakeup signal was found to be -54.8 dBm. The five portable base stations were found to have an average 2.45 GHz

output of -62.4 ± 6.96 dBm a difference of 7.6 dBm from the Zarlink ADK. Likewise, the Zarlink ADK was found to have a power output of -52.5 dBm at 400–405 MHz wavelength. The five portable base stations were found to have an average of -66.6 ± 2.98 dBm a difference of 14.1 dBm from the Zarlink ADK. Looking at the maximal peaks the Zarlink ADK had a maximum power output of -38.9 dBm at 2.45 GHz and -42.0 dBm at the 400–405 MHz wavelength. The portable base stations had an average maximal output at 2.45 GHz of -47.6 ± 9.46 dBm and an average power output on the 400–405 MHz wavelength of -49.8 ± 3.48 dBm. Individual performance results of the portable base stations are found in Table 4.4.

4.5 Discussion

4.5.1 Wireless Intravaginal Transducer Performance

After-calibration sensors are highly linear with an R^2 value of 1.0000, so we utilized a point-based linearity scheme in which the nonlinearity of the sensor expressed as deviation from a straight line passing through two points [21]. With this method we are able to adopt the AAMI standards for blood pressure transducer accuracy, which is within 1% between 0–68 cm H_2O and 3% between 68–350 cm H_2O [21]. The sensor deviation from linearity in Figure 4.3 shows all 10 sensors meet this standard.

Temperature, orientation and drift each add to the uncertainty of the recorded pressure value. It has been found that rectal temperature fluctuates between 37.4–37.8 °C between light and strenuous exercise [25]. With an average TCO of 0.54 cm H_2O/°C, this accounts for ± 0.7 cm H_2O shift during exercise once the sensor has reached thermal

equilibrium, approximately 10 minutes after placement in the upper vagina. This can be compensated by using the on-board TCO compensation of the ZMD signal conditioner or by recording temperature via the ZMD on-board thermistor and performing a posthoc calibration. Before use, the WIVT is placed on its side (0° angle) and zeroed to atmosphere for 30 seconds. During sensor placement in the vagina, the sensor is thought to be at an angle between 0 to 90° during standing activities and 0 to -90° during lying down activities. These orientation extremes from the atmospheric zero account for a range of ±2 cm H_2O due to orientation of the sensor alone.

The offset drift after 1.5 hours of use was on average -0.81 cm H_2O. Compounding multiple factors including orientation, TCO, and drift changes, the sensor has an accuracy of ±2.52 cm H_2O. The WIVT sensor orientation was found to be the largest contributor to this error. Thus, to achieve better accuracy of the WIVT, knowing the orientation of the sensor in the body with varying body positions would be helpful.

Five of the 10 sensors underwent in vivo use. During these in vivo trials there was no significant change in sensitivity of the trial devices from those that underwent bench top testing. However, it was found that sensitivity does change over time with an average change of -0.0071 counts/cm H_2O·day. These variations appeared to be both independent of manufacturing date and calibration date and instead dependent on the individual sensor. To minimize the chance of the battery capacity decline, each sensor is made 1 to 2 weeks before use. Over a 2-week period the average change in sensitivity is expected to be 0.01 counts/cm H_2O, which is a difference of 20 counts at 200 cm H_2O. In this scenario, if we assume an original sensitivity of 23 counts/cm H_2O, a 2-week drift in

sensitivity would drop intra-abdominal pressure from an actual value of 200.0 cm H_2O to a recorded value of 199.1 cm H_2O.

4.5.2 Portable Base Station Performance

Our ideal data capture rate for the WIVT is 32.26 Hz. Due to housekeeping protocols including a measurement for battery power and internal temperature, the time interval between measurements of 31 milliseconds could not be reliably maintained. This problem is further compounded by the communication between the WIVT and the portable or ADK base station. Monitoring five sensors with both the portable and ADK base station, the average acquisition rate was found to be 31.1 Hz. This did not differ significantly between devices.

The 2.45 GHz wakeup signal from the ADK base station had a power output of 7.7 dBm or 5.9 mW and the 400 MHz data line was 14.1 dBm or 25.7 mW greater. It was found that portable base stations had varying performance characteristics in both the 400 MHz and 2.45 GHz bands. Despite the variance in performance of the portable base stations, the placement of the portable base station was in close proximity to the WIVT, decreasing the need for wireless range over distance as with the ADK base station and computer.

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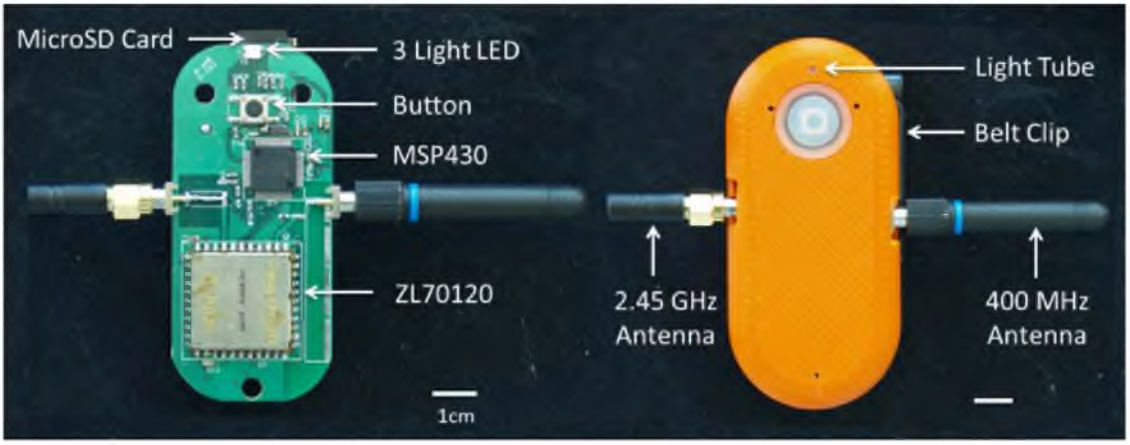

Figure 4.1. Photograph of the portable base station electronic board (left) and portable base station with cover (right). The base station contains a MSP430 that controls the Zarlink 70120 wireless chip, the 3-light LED, and MicroSD card for data storage. The button is used to activate the base station from a standby mode into an active mode initiating communication between the base station and the wireless intravaginal transducer.

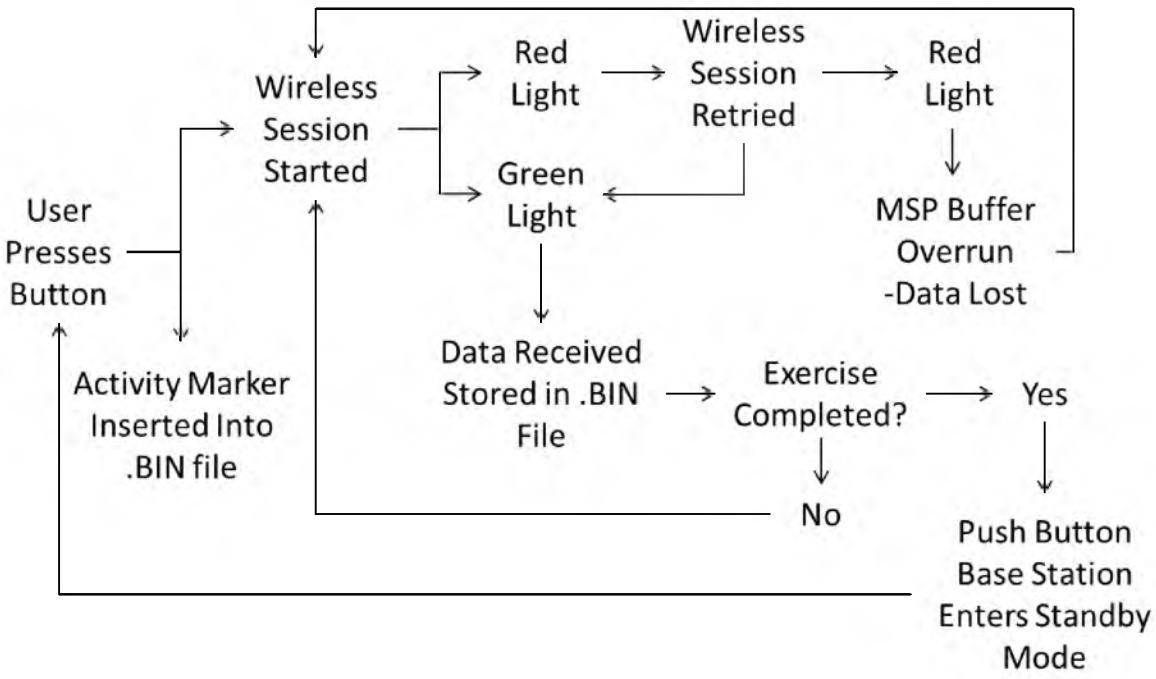

Figure 4.2. A flow chart representing the operation of the portable base station

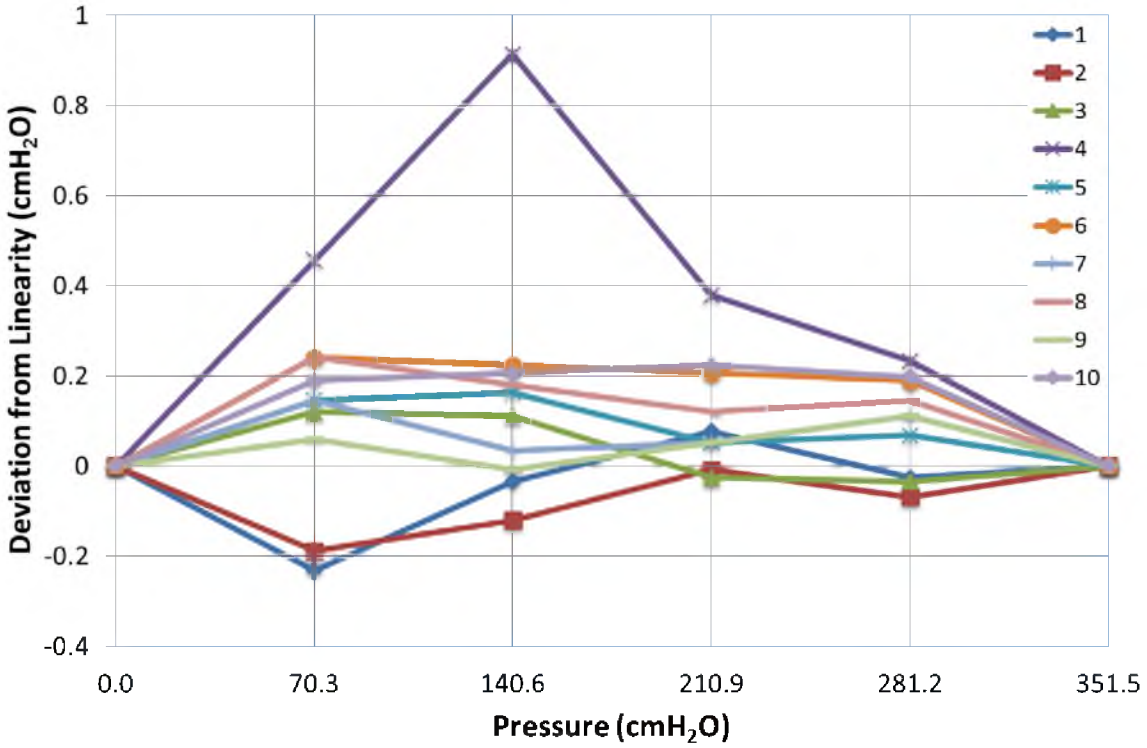

Figure 4.3. Graph of the deviation from linearity of 10 wireless intravaginal transducers during calibration from 0–351.5 cm H_2O. Data points 0 cm H_2O and 351.5 cm H_2O of each sensor were used to determine ideal linearity.

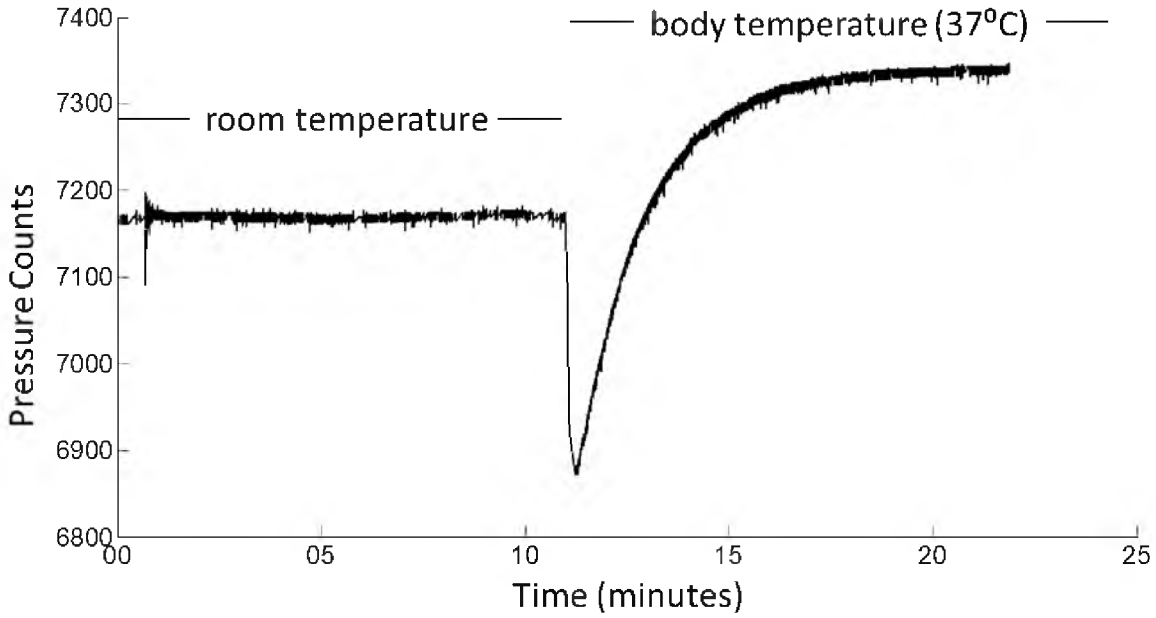

Figure 4.4. A typical graph illustrating the sensor offset change between room temperature and 37 °C in a water bath

Table 4.1 Temperature coefficient of offset (TCO) of 10 wireless intravaginal transducers

Sensor	23.5°C– 37° Temperature Counts	Pressure Increase ($cm H_2O$)	Pressure Increase ($cm H_2O$/ °C)
1	7194–7412	9.35	0.69
2	7170–7340	7.31	0.54
3	7939–8097	6.78	0.50
4	7447–7647	8.59	0.64
5	6726–6955	9.84	0.73
6	7567–7749	7.83	0.58
7	7710–7842	5.66	0.42
8	7757–7855	4.20	0.31
9	7529–7681	6.50	0.48
10	7538–7761	9.59	0.71
	Average	7.56	0.56
	SD	1.84	0.14

Table 4.2 Sensitivity change of 10 wireless intravaginal transducers comparing in vivo use to non in vivo use

In-vivo use			No in-vivo use		
Sensor	**Days**	**Sensitivity Change (counts/cmH_2O)**	**Sensor**	**Days**	**Sensitivity Change (counts/cmH_2O)**
2	54	-0.097	1	54	-0.825
3	34	-0.502	4	34	-0.308
5	35	-0.020	6	22	0.031
7	26	-0.389	8	26	0.098
9	34	-0.576	10	34	-0.090
Average sensitivity change per day		-0.0098 (counts/cmH_2O·day)	Average sensitivity change per day		-0.0044 (counts/cmH_2O·day)

Table 4.3 Acquisition rate of the ADK base station and portable base station

Sensor	**ADK Base Station Acquisition Rate (Hz)**	**Portable Base Station Acquisition Rate (Hz)**
1	31.4	31.9
2	31.9	30.4
6	29.4	31.3
7	31.4	30.3
9	31.4	31.9
Average	31.10	31.16
SD	0.967	0.767

Table 4.4 Base station power output at the 2.45 GHz and 405 MHz wavelengths

Base Station	Peak Frequency (GHz)	Avearage Peak (dBm)	Maximal Peak (dBm)	Peak Frequency (MHz)	Average Peak (dBm)	Maximal Peak (dBm)
ADK	2.450	-54.8	-38.9	405	-52.5	-42.0
PBS 1	2.450	-62.2	-46.7	403	-65.5	-48.6
PBS 2	2.450	-72.1	-62.5	403	-66.5	-47.2
PBS 3	2.450	-57.5	-41.2	405	-64.2	-47.1
PBS 4	2.450	-54.5	-38.1	403	-65.1	-50.7
PBS 5	2.450	-65.9	-49.6	404	-71.8	-55.5

CHAPTER 5

CREATING A LOW INTRA-ABDOMINAL PRESSURE POSTSURGICAL EXERCISE ROUTINE USING THE PILATES METHODOLOGY

5.1 Abstract

5.1.1 Aims

To monitor and describe intra-abdominal pressures generated during Pilates Mat and Reformer activities and determine whether these activities generate IAP above a sit-to-stand threshold. Using this threshold a Pilates routine will be identified for postpelvic floor surgery exercise where the maximum intra-abdominal pressure is below the currently accepted sit-to-stand threshold.

5.1.2 Methods

Twenty women, median age 43 (range 22–59 years; body mass index 22.6 ± 2.3 kg/m^2), completed Pilates Mat and Reformer exercise routines each consisting of 11 exercises. Intra-abdominal pressure data were collected by an intravaginal pressure transducer, transmitted wirelessly to a base station, and analyzed for maximal, area under the curve (AUC), and first moment of area intra-abdominal pressure.

5.1.3 Results

In general no Pilates exercise was found to have mean max IAP statistically greater ($p < 0.05$) than sit-to-stand, although a few participants exceeded their individual threshold in a few exercises. Pilates Reformer roll-up and Pilates Mat roll-up had AUC statistically higher ($p < 0.05$) than sit-to-stand after applying a threshold.

5.1.4 Conclusion

A low intra-abdominal pressure exercise routine was developed using an intravaginal pressure sensor. The exercise protocol consists of 10 Pilates Mat and 10 Pilates Reformer exercises. More research is needed to determine the long term effects of Pilates exercise on postsurgical exercise rehabilitation and pelvic floor health.

5.2 Introduction

Nearly 24% of women in the United States have a symptomatic pelvic floor disorder (PFD) [1]. Pelvic floor disorders consist of urinary incontinence (UI) and pelvic organ prolapse (POP) and can drastically change lifestyle and exercise practices of women. As a result, many women undergo a surgical procedure to repair the pelvic floor. In 1997 an estimated 289,000 women underwent an inpatient surgical procedure to correct a PFD [2], [3], and around 30% of women will return for surgical reoperation [4]. American women have an 11.1% lifetime risk of undergoing pelvic floor surgery. Although the rate of POP-related surgical procedures has decreased slightly, the rate of UI surgeries has nearly doubled in the last 2 decades [2]–[4].

Due to the relationship between intra-abdominal pressure (IAP) and physical activity, clinicians often recommend drastic long-term activity restrictions (lifting, climbing stairs, etc.) for women with existing PFD or after surgical repair [5]–[7]. The restrictions are prescribed in an effort to minimize IAP, which is thought to increase the breakdown of surgical repair or further exacerbate the PFD [6]. Many of these postsurgical activity restrictions are based upon individual viewpoints and vary widely in severity and duration [8]. The insufficiency of mobile IAP monitoring capability and the unproven relationship between exercise and PFD have resulted in a lack of postsurgical activity promotion. To overcome these shortcomings, a wireless remote abdominal pressure system was developed to accurately track IAP during activity [9], [10].

In order to develop a low intra-abdominal exercise routine, an activity must be chosen to act as a threshold in which to compare other activities. Postoperative activity restrictions typically do not include limiting a patient from standing from a seated position [5]. Recently, this group tracked IAP in 57 women during a standard exercise session that included sit-to-stand activity. Results from this study revealed that sit-to-stand produced a moderate increase in IAP, which was documented in a similar study by Weir et al. in 2006 [5], [11]. Sit-to-stand will be compared to Pilates exercise due to its accessibility, documented health benefits, and its use in a rehabilitative setting.

Pilates exercise is largely performed on either a padded Mat or Pilates Reformer exercise apparatus. The Pilates Reformer is highly adaptable to individual users, which is why it has gained use as a rehabilitation tool for foot and ankle injuries and after total hip or knee arthroplasty [12]–[14]. Pilates Mat exercises can be the most challenging of all

Pilates exercises due to the lack of supportive equipment, such as a Reformer, but can be performed at home [13]. There are many documented benefits to regular participation in Pilates, including increased flexibility [15], improved dynamic standing balance [16], increased abdominal and upper body muscular endurance [17], improved postural alignment [17], and improved strength of the pelvic floor [18]. People who maintain or improve their flexibility are better able to perform daily activities, be less likely to develop back pain, and avoid disability especially as they age [19]. Therefore, it is in the best interest of women, at an increased age and consequently at an elevated risk of a recurrent PFD, to be maximally active after surgery without increasing the risk to an already weakened pelvic floor. We hypothesize that a low IAP exercise routine can be formulated by monitoring women during a Pilates Mat and Reformer exercise class, and we will use the data to determine which Pilates exercises exceed the sit-to-stand threshold and eliminate activities that exceed the threshold. With the formulation of a low intra-abdominal pressure exercise protocol, there is an opportunity for women to maintain or improve their exercise habits during their postsurgical recovery period.

The primary aim of this study is to monitor and describe IAP during Pilates Mat and Reformer activities and determine if these activities are above the sit-to-stand threshold. The secondary aim is to compare selected Mat and Reformer activities to determine if one methodology is significantly different than the other.

5.3 Methods

5.3.1 Exercise Protocol

Prior to the study each participant signed informed consent forms approved by the University of Utah Institutional Review Board. Participants recruited were women between the ages 18 to 60 years, BMI 19–30, and who had prior Pilates experience. Participants were excluded if they responded positively to any question on the Physical Activity Readiness Questionnaire [20], were currently pregnant, within 6-months postpartum, or had an injury that would interfere with completion of the exercise protocol.

Each participant was given written instructions that described the proper method on self-inserting the wireless intravaginal transducer (WIVT) after voiding their bladder as in previous studies [11], [21]. Intra-abdominal pressure was monitored by the wireless remote abdominal pressure system, which consists of a WIVT and a portable base station. The WIVT contains a piezoresistive pressure sensor, microcontroller, and wireless transceiver that is sealed in an elastomeric capsule filled with silicone gel [9]. Data from the WIVT are sent wirelessly to a portable base station located on the participant's hip that stores data on a microSD card. Each sensor was preheated to 37 °C and zeroed to atmospheric pressure prior to use. During the study, the Pilates instructor directed the participants to press an interface button located on the base station at the beginning and end of each activity (22 activities in total) to start and stop data acquisition. During each activity, the study coordinator would confirm the presence of a green blinking light on participant's base station to indicate that the participant depressed the interface button

appropriately and wireless communication, was proceeding. If no light was present, indicating that the button was not pressed properly, or a red LED light was present, indicating failed wireless communication then the study coordinator would take corrective action by adjusting the position of the base station to achieve communication or in severe cases replacing the sensor with a new sensor.

To start the Pilates session, each participant was monitored during five baseline activities, supine, side-lying, prone, quadruped, and standing, and one threshold activity: multiple sit-to-stand with hands crossed on chest to a metronome of 40 bpm. Next, all participants, in a class ranging from 1–4 participants, completed either the 11 Pilates Mat followed by 11 Pilates Reformer exercises or vice versa depending on alternating study days. Each of the 22 Pilates exercises lasted approximately 1 minute, consisting of between 4–8 repetitions, with the entire protocol lasting approximately 1 hour. Rest times between exercises were not standardized in order to best represent a class environment. At times the study protocol was paused if wireless transmission difficulty was encountered, or if a WIVT was displaced from the upper vagina during exercise. If the WIVT was displaced during exercise, the participant was allowed to go to the restroom to readjust the sensor, repeat the activity, and continue with the exercise routine.

After conclusion of the exercise protocol, participants completed a history form that included age, weight, height, number of pregnancies lasting 20 weeks of gestation, number of Cesarean sections, number of vaginal deliveries, hysterectomy, length of Pilates practice, frequency in last 6 months using Pilates exercise, and whether the sensor fell out during the study. IAP data were assessed for completeness. Baseline and

threshold activities were considered for analysis if data length was greater than 10 seconds. A Pilates activity was considered for analysis only if data were present for at least 75% of the total activity time as monitored by stopwatch. If these thresholds were not achieved, due to deficient wireless communication or participant error in initiating the start of wireless data acquisition, then the activity was considered incomplete and excluded from analysis.

5.3.2 Waveform Evaluation

A custom Matlab software (R2011A, MathWorks) program was used to evaluate the pressure data as previously described [21]. Maximal IAP was calculated by averaging the 10 maximal peaks in the waveform each separated by 1 second. Area under the curve (AUC) was calculated by use of trapezoidal approximation. First Moment of Area (FMA) was determined by squaring the pressure amplitude before applying a trapezoidal approximation. Each exercise in the study consisted of a variable length, which is used to calculate AUC and FMA resulting in cm $H_2O \cdot s$ and cm $H_2O^2 \cdot s$, respectively. In an effort to compare these values, our previous study standardized AUC and FMA by dividing by the activity length in seconds [21]. This calculation results in a ratio number that allows one to compare IAP of different activities as a time-weighted average, but it is not a true AUC. In this study instead of normalizing AUC and FMA values, the true values were reported along with AUC and FMA above a threshold in order to compare the severity of activities.

5.3.3 Descriptive Statistical Analysis

To determine the number of participants needed in the study a power analysis was performed using the average and standard deviation of sit-to-stand mean max values from a previous study [11]. Using these statistics ($\alpha = 0.05$, $p = 0.80$), it was determined that a statistically discernible difference of 10 cm H_2O could be detected in 20 people with 2-sided tests.

To assess normality of data, a Lilliefors test was used [22]. A Wilcoxon signed-rank test ($\alpha = 0.05$) was used to determine whether exercises were significantly different from sit-to-stand activity. Likewise a Wilcoxon signed rank test was used to make five comparisons between Reformer and Mat activities, which included side-kick versus side-kick, long stretch versus plank, feet-in-straps versus leg circles, supine abdominals versus the hundred, and roll-up versus roll-up, respectively. A Spearman rank correlation was used to explore the correlation between BMI, age, and experience with maximal peak IAP during the Pilates Mat roll-up. During Spearman rank calculations significance was accepted at $p < 0.05$. All tests were two-sided. All statistics were calculated using a custom Matlab program with loaded statistics package.

5.4 Results

5.4.1 Subject Statistics

Twenty women were enrolled in the study. Their mean age was 43.1 years (range: 22–59), mean body mass index was 22.6 kg/m2 (SD 2.3), and 30% were nulliparous. All 20 women completed the exercise routine. Two women were excluded from data analysis

due to failure of device retention as indicated on participant surveys as well as abnormally low pressure data.

5.4.2 Descriptive Analysis

Based upon a Lilliefors test for normality, results were generally consistent with normality, with the exception of three activities when analyzing mean max IAP, one activity when analyzing AUC, and 10 activities when evaluating FMA. For simplicity, all tests are Wilcoxon tests. The mean and range IAP during baseline activities are shown in Table 5.1. Descriptive measures and statistical significance of mean maximal IAP and AUC for the sit-to-stand activity as well as Pilates Mat and Reformer exercises are shown in Table 5.2. Analyzing mean max IAP, no activities were found to be statistically greater than sit-to-stand, but the Pilates Reformer roll-up was not detectably different from sit-to-stand ($p > 0.05$) (Figure 5.1). The percentage of individual women exceeding their mean max IAP + SD for sit-to-stand on a particular exercise is shown in Figure 5.1. AUC was analyzed in two ways. The first presents AUC unaltered from the exercise study (Figure 5.2); the second calculates AUC above 40 cm H_2O (Figure 5.3). Based upon AUC above 40 cm H_2O, both Pilates Reformer and Mat roll-up were found to incur IAP statistically higher ($p < 0.05$) than the sit-to-stand activity (Figure 5.3). Mat standing leg raise, plank, and swan along with Reformer kneeling arm work, swan, long stretch, and side split were found to be statistically indistinguishable ($p > 0.05$) from sit-to-stand. All other exercises were statistically below ($p < 0.05$) sit-to-stand. FMA results did not produce any additional insight and closely followed AUC measurements.

5.4.3 Difference between Reformer and Mat Exercises

Out of the five comparisons made between Pilates Mat and Reformer exercises, no statistically significant difference ($p > 0.05$) was found when analyzing mean maximal IAP. The Reformer roll-up was found to be significantly greater ($p < 0.05$) in both AUC and FMA.

5.4.4 Correlation Analysis

Spearman correlations between Pilates experience and age versus IAP mean max were generally not significant except for experience versus mean max Reformer roll-up (rho = -0.54) and age versus mean max Mat roll-up (rho = 0.69). Correlations between BMI and mean max IAP were significant in 8 of the 22 Pilates exercises with rho values ranging between 0.49–0.68.

5.5 Discussion

5.5.1 Pilates Exercise Versus Threshold Activities

There are many benefits to Pilates exercise, including the findings by Culligan et al. in 2010 where a Pilates exercise routine was found to be as effective in increasing pelvic floor muscle strength as a traditional pelvic floor muscle training routine [18]. However, it is unclear how Pilates exercises influence the loading and the health of the pelvic floor. A recent study revealed the incidence of stress urinary incontinence among Pilates and Yoga group fitness instructors to be 15.2% [23]. This prevalence rate is slightly higher when compared to stress UI in a community setting (10.7%), but lower than that

of women during exercise such as running 38%, low-impact aerobics 22%, and walking 21% [24], [25]. The study of UI among Pilates and Yoga fitness instructors simultaneously hinted at the potential for Pilates exercise to expose users to increased IAP, but at the same time to have a lower risk of UI, when compared to other forms of exercise. In general this study showed that Pilates exercise did not expose users to high spikes in IAP above their sit-to-stand threshold except for a few participants. However, area under the curve measurements revealed that the Pilates Mat and Reformer roll-up exposed participants to statistically higher cumulative IAP than the threshold activity.

One of the challenges of this study was to determine a threshold activity to which all other activities could be compared. Current postoperative clinical restrictions generally do not include prohibiting the patient from standing up from a seated position. One problem encountered during this study is the AUC comparison between an activities such as sit-to-stand with an activity that may last longer. Sit-to-stand was performed on average 20 times during a duration of 28 seconds, while the range of average time spent on each Pilates exercise was 48–94 seconds. We chose to compare AUC by setting a 40 cm H_2O threshold for calculating AUC to compare IAP severity of activities that are low IAP with a long duration to those that are high IAP with a short duration. Standing peak pressures in the literature ranges from 16–29 cm H_2O and, from our understanding, breathing increases IAP anywhere from 1–5 cm H_2O [26]. Combining these two factors, it is conceivable that a person while standing can reach 35 cm H_2O. Adding a 5 cm H_2O increase to this estimated maximum results in a 40 cm H_2O threshold in which normal standing pressures would not contribute but with the addition of movement and

breathing could overcome the threshold.

Overall, to place the Pilates exercise routine into perspective, preliminary data were obtained from our concurrent study of 46 women during slow walking. During slow walking 400 meters, averaging 1.9 miles per hour, participants generated on average 15,512 cm H_2O·sec in 465 seconds. We then estimated the activity performed by patients recovering from surgery to include sit-to-stand (including while voiding) 20 times and walking for 5 minutes three times in a 24 hour period. Based upon this profile, sit-to-stand measurements obtained in this study and preliminary walking data, an estimation of postsurgical AUC is 31,136 cm H_2O·sec, which is compared to the total AUC for Pilates exercise in Figure 5.4. Area under the curve measurements describing intra-abdominal pressure are used very little in the literature [21], [27]. However, AUC is commonly used in endocrinological and neuroscience research to comprise information that is contained in repeated measures over time. AUC is used to determine the effects of medication over a time period or to evaluate dose and response relationships that closely resemble the exercise and pelvic floor health relationship [28].

Baseline pressure for standing was found to be within previously established ranges performed during urodynamic studies [29], [30], yet were slightly higher than those reported by O'Dell et al. [26]. The mean sit-to-stand threshold of 56 cm H_2O is a 14 cm H_2O less than what was reported previously but still well within the previous range [5]. Many studies measuring IAP report maximum values, as it is currently believed that pelvic floor failure occurs when an event (forceful exercise or childbirth) causes pelvic floor strain resulting in stretching or tearing of muscles and connective tissue but may not

become apparent until decades after the trauma [31].

5.5.2 Reformer Versus Mat Activities

In the five Mat and Reformer exercises compared, only the Pilates Reformer roll-up produced statistically higher IAP ($p < 0.05$) for AUC and FMA. Typical pressure curve comparisons for Reformer and Mat are shown in Figures 5.5 and 5.6. One possible explanation for the statistical difference between roll-up on Mat and Reformer is the participant was unable to fully relax during the Pilates Reformer movement as spring tension continued to pull the participant upwards during the relax phase which was not present in the Mat activity (Figure 5.3).

5.5.3 Postsurgical Exercise and Recommendations

The 22 Pilates exercises were designed to closely resemble an introductory Mat and Reformer class. Based upon these results, Pilates exercises do not generate as large of an increase in IAP as the sit-to-stand activity. However, many Pilates methodologies exist, some teaching active engagement of the pelvic floor, in which case this study only begins to explore how IAP relates to Pilates exercise and should be treated as a guide. Based upon results, in order to create a low intra-abdominal pressure postsurgical exercise routine where the IAP does not exceed sit-to-stand, all activities described in this study can be utilized except for the Mat and Reformer roll-up.

There is still a question as to the convalescence time before starting postsurgical activity, which is beyond the scope of this study. However, in one study it was found that

the most frequent contributing factor to resume activities were fatigue, pain, and fear of pain. Furthermore, it was found that nonrestrictive recommendations do not seem to influence short-term subjective recurrence of prolapse [30]. No published data monitoring the healing of the pelvic floor or the effect of increased IAP on the rate of wound healing and strength are available. Therefore, it is not possible to design a postoperative activity program that would protect the healing of the wound or promote eventual wound strength [7]. The goal of this study was to design an exercise routine that can be performed after pelvic floor surgery to keep women active while minimizing IAP.

5.5.4 Limitations

Rest periods between activities were not controlled, as in a real world setting, potentially contributing to an additive effect on IAP during later activities. Order of mat versus Reformer Pilates was not randomized, but was alternated by study day with 50 % of participants starting with Pilates Mat. Breath control, which has been shown to contribute to the magnitude of peak IAP, was cued during the exercise by the movement practitioner [31]. However, the synchronization of movement and breath was not verified and is a likely contributor to IAP variability. This study indirectly measured IAP in the upper vagina, which has been shown to correlate with urodynamic testing values [10], [32]–[34]. However, an indirect measurement of IAP rather than a directly measuring IAP in the abdominal cavity adds uncertainty including forces from the viscera, smooth muscle contractions, and others. The placement of measurement device in the upper vagina subjects the sensor to the same forces that are present on the pelvic floor since the pelvic

and abdominal cavities are closed systems. Based upon previous exercise studies performed using the wireless remote intra-abdominal pressure system it is reasonable to assume that data collected were a combination of the forces of the upper vagina and pelvic muscle contraction, though it is possible that in some women IAP was measured in the lower vagina due to sensor displacement during exercise [11].

Participants in this study were healthy and active women with varying levels of Pilates exercise experience in order to decrease the risk of adverse events during exercise participation. Therefore, the pressures acquired during this study cannot be generalized to less active women with chronic conditions.

5.6 Acknowledgements

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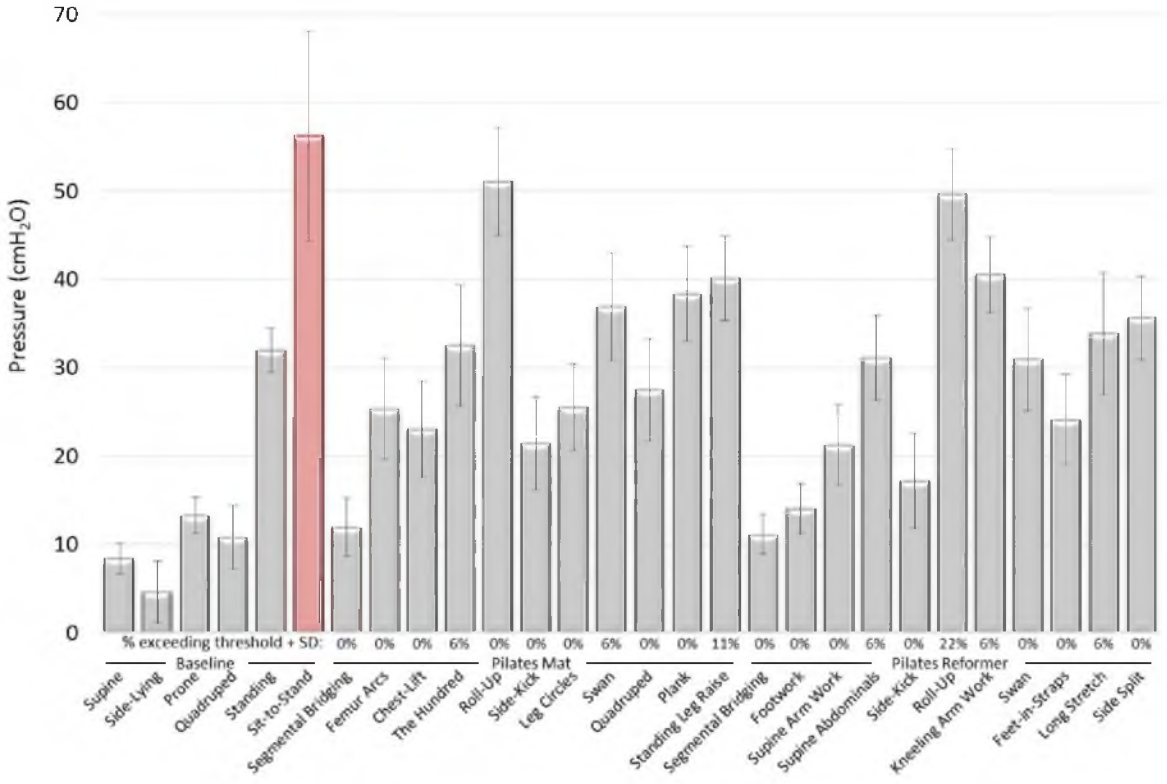

Figure 5.1. Bar graph of mean max IAP ± 95% CI during 5 baseline activities, threshold, 11 Pilates Mat activities, and 11 Pilates Reformer activities. The percentage of participants exceeding their individual threshold + standard deviation of threshold on a particular exercise is shown below the graph.

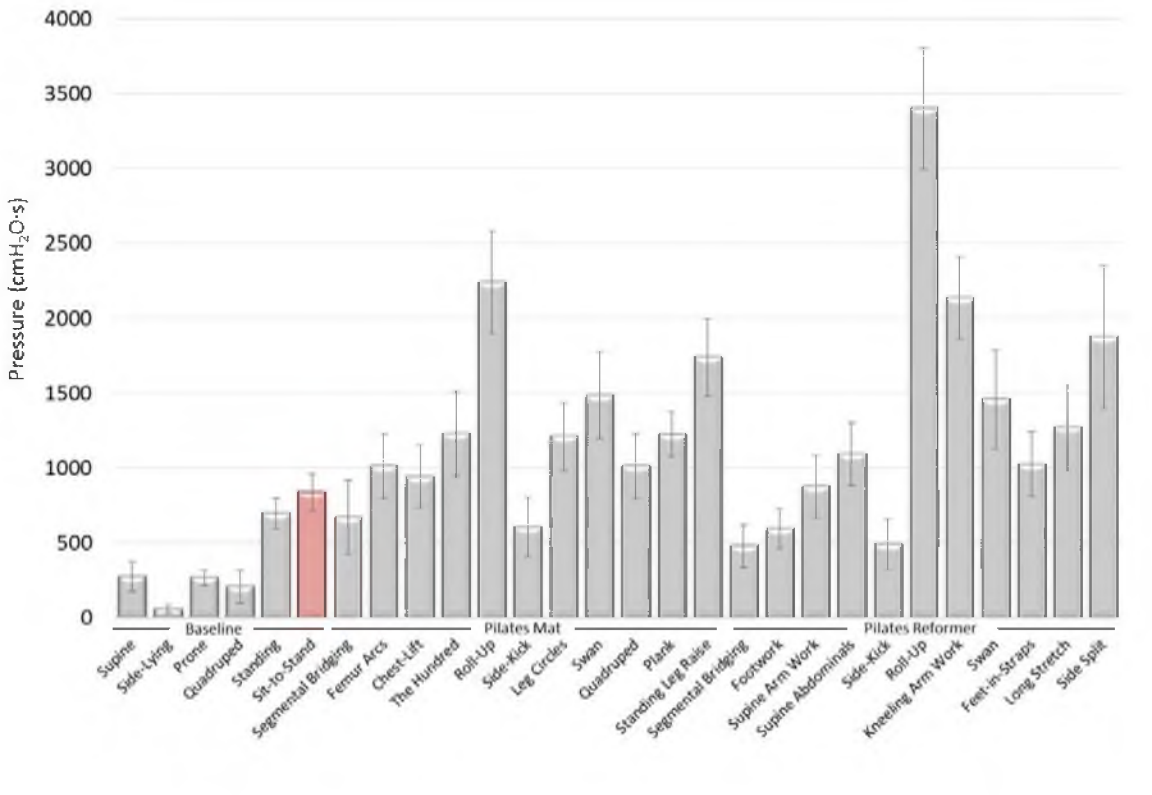

Figure 5.2. Bar graph of area under the curve (AUC) ± 95% CI during 5 baseline activities, threshold, 11 Pilates Mat activities, and 11 Pilates Reformer activities

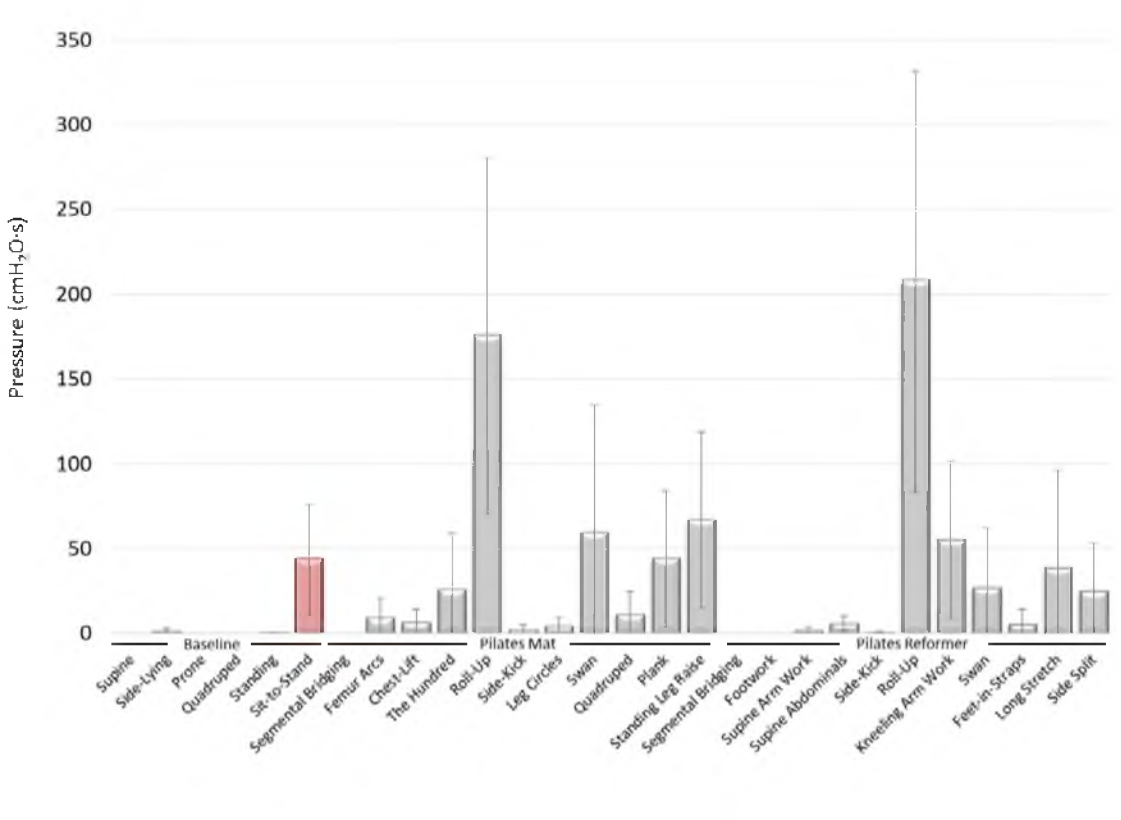

Figure 5.3. Bar graph of area under the curve (AUC) above 40 cm H_2O ± 95% CI during 5 baseline activities, threshold, 11 Pilates Mat activities, and 11 Pilates Reformer activities

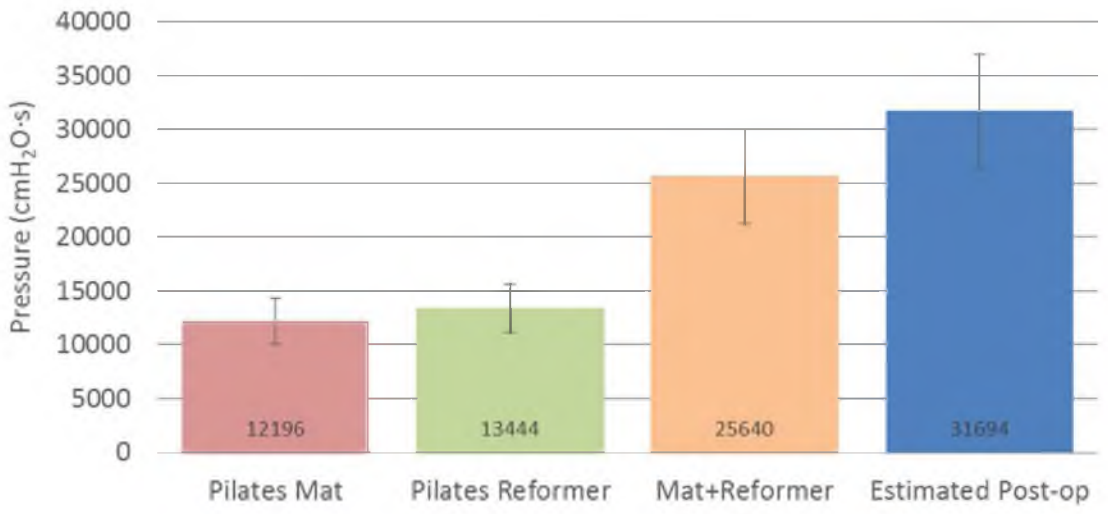

Figure 5.4. Total area under the curve ± 95% CI profiles for Pilates Mat (30 min), Pilates Reformer (30 min), Pilates Mat and Reformer (60 min), and lower range activity profile of postsurgical patient consisting of 20 sit-to-stand (including voiding periods) and walking 15 minutes at a slow pace as if walking with an elderly person

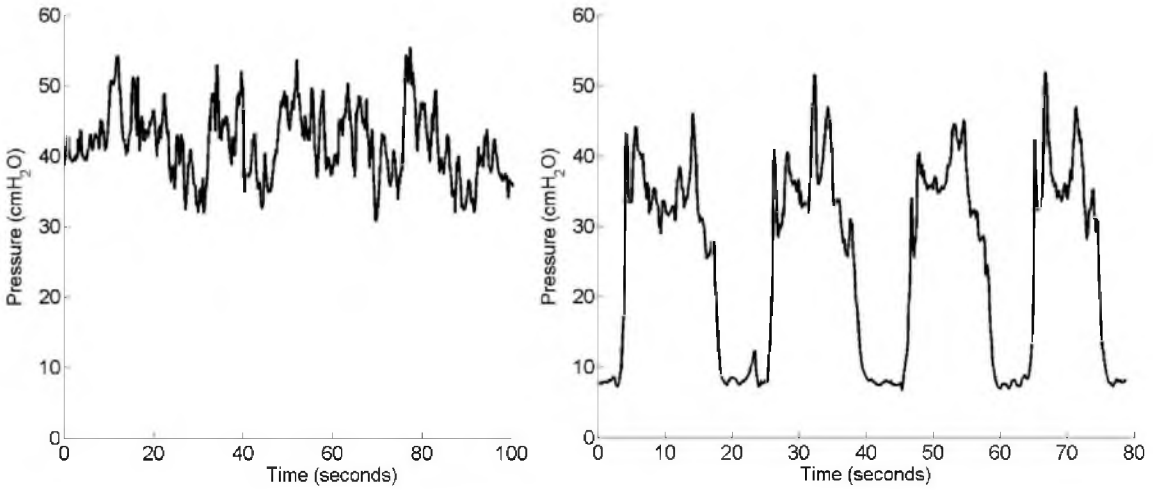

Figure 5.5. Typical intra-abdominal pressure measurement while participant performs A) Pilates Reformer roll-up and B) Pilates Mat roll-up

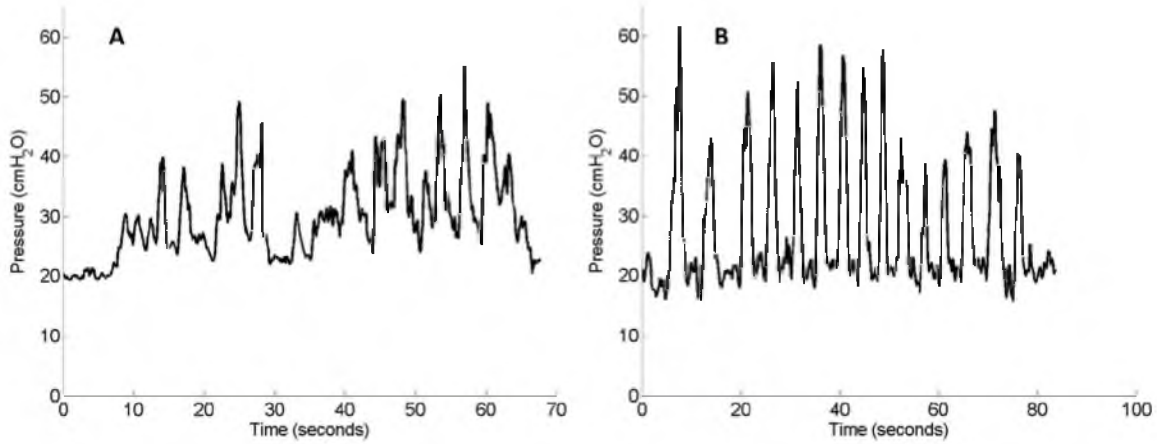

Figure 5.6. Typical intra-abdominal pressure measurement while participant performs A) Pilates Mat leg circles and B) Pilates Reformer feet-in-straps

Table 5.1. Mean IAP during baseline activities

ACTIVITY	N	Mean IAP (SD)	Range
Supine	18	6.6 (3.2)	-3.3– 10.7
Side-Lying	18	1.2 (2.5)	-3.6– 4.6
Prone	18	9.2 (3.5)	4.4– 15.2
Quadruped	17	6 (6.8)	-5.5– 18.7
Standing	18	28.9 (4.8)	21.8– 37.2

Table 5.2. Descriptive measures for sit-to-stand, Pilates Mat, and Pilates Reformer exercises

ACTIVITY	N	Mean Maximal IAP	Range Maximal IAP	Mean AUC (SD)	Range AUC
Threshold Activity					
Sit-to-Stand	18	56.2 (25.7)	35.9-144.3	835.5 (271.4)	331.2– 1459.8
Pilates Mat Exercises					
Segmental Bridging	16	12 (7.2)	3.9-30.4	673.4 (534.4)	112.9– 2105.4
Femur Arcs	17	25.4 (12.3)	8.8-51.5	1013.5 (465.6)	389.7– 1997.4
Chest-Lift	16	23 (11.8)	5.8-52.1	944 (459.4)	222.3– 2143.5
The Hundred	17	32.6 (14.9)	10-69.2	1227.9 (609.2)*	254.6– 2501.8
Roll-Up	15	51.1 (13.2)	33.2-75.7	2240.3 (743.3)**	1016.4– 3441.8
Side-Kick	13	21.5 (11.4)	4.3-40.3	606.8 (431.4)	104.5– 1632.1
Leg Circles	18	25.5 (10.6)	11.5-48.3	1212 (496.2)*	327.3– 2058
Swan	17	36.9 (13.3)	11.9-68.1	1483.9 (627.5)*	459.3– 2993.9
Quadruped	16	27.5 (12.6)	8.4-53.6	1011.2 (470.2)	258.9– 1932.2
Plank	16	38.4 (11.7)	22.8-59.6	1223.5 (326.1)*	725.1– 1835.2
Standing Leg Raise	18	40.1 (10.4)	27-63.4	1736.8 (569)*	813.8– 2671.8
Pilates Reformer Exercises					
Segmental Bridging	17	11.1 (4.9)	4.1-21.3	479.2 (305.5)	64.3– 1051.1
Footwork	16	14.1 (6.1)	5.1-23.5	596.5 (289.7)	175.1– 1227
Supine Arm Work	17	21.3 (9.9)	10.8-44.8	876.9 (452.5)	314.5– 1967.1
Supine Abdominals	16	31.1 (10.4)	11.1-45.8	1095.9 (450.7)	353.2– 1938.1
Side-Kick	16	17.2 (11.6)	2.4-34.2	493.5 (360.3)	25.9– 1088.3
Roll-Up	16	49.6 (11.2)	29.1-74.2	3400.7 (873.2)**	1664.7– 5020.2
Kneeling Arm Work	15	40.5 (9.2)	20-54.1	2133.8 (590.4)*	1269.1– 3096
Swan	17	30.9 (12.5)	10.8-61	1457 (706.6)*	457.8– 2746.3
Feet-in-Straps	17	24.1 (11.2)	9.5-54	1024.9 (471.2)	389.6– 2253.8
Long Stretch	17	33.9 (15)	1.6-69	1270.6 (627.2)*	55.3– 2858.7
Side Split	18	35.6 (10.3)	6.9-50.5	1875.2 (1026.3)*	265.3– 3385.5

* Statistically greater than sit to stand threshold

** Statistically greater than sit to stand after subtracting 40 cmH_2O

CHAPTER 6

SUMMARY, CONCLUSIONS, AND FUTURE WORK

6.1 Summary and Applications

There are a number of compelling reasons to measure intra-abdominal pressure (IAP). The work in this thesis was motivated by the current lack of understanding of the role that IAP plays in the pathogenesis of pelvic floor disorders and the lack of objective guidelines for postsurgical activity restrictions in women recovering from pelvic floor surgery. The current clinical standard for measurement of IAP is conducted using a rectal balloon catheter coupled to an external pressure transducer. While this system is able to measure IAP, there are a number of shortcomings. It requires a complicated setup, offers poor dynamic response, and the use of bulky cystometry machines makes this technology impractical for measuring IAP outside of the clinic [1].

To overcome these shortcomings, a novel pressure sensor was developed in 2009 that allowed for IAP measurement in the nonfluid-filled environment of the upper vagina. Subsequent benchtop testing demonstrated improved dynamic response over the gold standard rectal balloon catheter with external pressure transducer [1]. The proof-of-principle intravaginal transducer (GEN1 IVT) demonstrated that IAP can be accurately monitored by placing a sensor within the intravaginal compartment. After input from

clinicians and patients, further modifications were needed to improve the reliability, durability, and portability of the device. To address reliability and durability concerns, it was hypothesized that an incompressible silicone gel could replace saline in transferring the pressure from external forces of the capsule to the sensor die. Bench testing validated the integration of the silicone gel by subjecting the analog GEN1 prototypes to benchtop tests including swept sine wave, impulse, temperature coefficient of offset, and sensitivity testing (see Appendix A) [2].

The fourth revision design of the elastomeric capsule proved to be both retained in the upper vagina during exercise, was comfortable to users, and accurately tracked IAP compared to the rectal balloon catheter in the clinic [3], [4].

In 2009 Johnson et al. designed a wired prototype that measured 1.3 cm in diameter by 2.7 cm in length [1]. Using pelvic floor models, it was postulated that this design was small enough to fit into the upper third of the vagina and be retained by wedging itself anteriorly between the anterior fornix. Capsule design Rev 2 measured 1.6 cm in diameter and 3.5 cm in length, which was not retained in the upper vagina during exercise. Using the pelvic floor model, it was found that the diameter of the Rev 2 capsule was too large to fit into the anterior fornix. Rev 3 capsule design measuring 2.4 cm in diameter and 2.7 cm in length was found to be retained during exercise. It was hypothesized that the Rev 3 design was large enough to be supported by the vaginal canal, which has an average diameter of 2.5 cm but widens near the cervix [5]. Likewise, the Rev4 design consisted of a starting diameter of 2.4 cm, tapering to 1.5 cm before ending in a rounded terminus. The overall length of the Rev 4 design was 3.7 cm in length. Out

of 106 women monitored by the wireless IVT, the retention failure rate, which consisted of participants thinking the sensor slipped into their lower vagina or into their underwear, was 11% with the majority of the sensors slipping into the lover vagina. In clinical practice, many sizes and shapes of pessaries are made to best suit women's needs. To improve retention in the future, many sized for the Rev 4 capsule design could be made to better fit women with anatomic variations.

Rev 2 and 4 capsule designs were found to accurately track IAP in a clinic setting while Rev 3 did not [4]. It is possible the length and shape of the Rev 3 device prevented women from properly inserting the device in the upper vagina. The Rev 4 capsule design was longer and therefore reached the upper vaginal space. The Rev 4 capsule proved that it could be comfortable for participants, be retained in the upper vagina during exercise, and accurately track changes in IAP. Given that Rev 4 met these requirements, no further studies were conducted to further optimize the system to improve retention or pressure monitoring.

In Chapter 3 of this dissertation I describe the development of a wireless IVT (GEN2). The results of this development and testing phase demonstrate the ability of the wireless IVT to accurately and reliably measure pressure when compared to the analog GEN1 IVT. The improvements to the first generation design were verified and validated using both bench top and clinical testing (see Appendix B for clinical testing results). The GEN2 IVT was found to be highly linear, generates robust signal transmission, and provides dynamic response, which outperforms the clinical standard [6]. The integration of an analog-to-digital signal processor allows the atmospheric and temperature offset to

be eliminated from the system while controlling the gain (sensitivity). Wireless signal transmission allows the versatility of free movement within a supervised exercise setting while establishing the foundation for future development of an on-person base station.

The wireless intravaginal transducer allowed IAP pressure measurements during two sessions of 31 exercises, each lasting approximately 30 seconds (see Appendix D) [7]. The data obtained in that study allowed researchers to describe novel methods of maximal peak, area under the curve, and first moment of area measurements from a number of activities and exercises (see Appendix C) [3].

Several types of errors can be found in all types of physiologic pressure transducers. The most common are 1) temperature errors, which alter the output of the sensor at any given pressure due to changes in temperature [8]; 2) Offset errors, also known as baseline drift and defined as the change in sensor output at zero pressure [9]; 3) sensitivity errors, also known as gain errors, which occur when the slope of the pressure/output curve varies with time [8]; and 4) drift errors, which occur when a sensor's original calibration constants change during use [10]. Most of these errors can be minimized through the careful design of the sensor, packaging, and electronics. The Association for the Advancement of Medical Instrumentation (AAMI) established a standard for blood pressure measurement, accuracy, and verification testing as outlined in the TIR:9 1992 and BP:22 1994 [11], [12]. These standards are widely used and applied to other forms of physiologic pressure measurement.

Chapter 4 of this dissertation describes further verification testing of the Wireless Remote Abdominal Pressure System (WRAPS) to provide additional evidence supporting

previous clinical findings and further establish a performance baseline for future design modifications. Adequate characterization of the WRAPS is pivotal for expanded testing outside of a laboratory environment where experimental factors cannot be tightly controlled and anticipated. The wireless intravaginal transducer (WIVT) was found to have a deviation from linearity less than 1% between 0–350 cm H_2O, which meets the AAMI standards [11], [12]. The 10 sensors tested had an average temperature coefficient of offset of 0.54 cm H_2O/°C which could automatically be compensated for use using the onboard thermistor associated with the ZMD. However, a post-study analysis revealed that water head pressure during temperature cycling resulted in a pressure increase of between 1.0–1.8 cm H_2O with an average increase of 1.36 cm H_2O. Future temperature cycles will monitor and account for this increase in pressure during temperature cycling. Sensor offset was found to change with respect to sensor orientation due to the mass of the silicone gel. During benchtop testing, it was found that the offset of the WIVT changed by an average of 2 cm H_2O from upright to inverted positions. To further characterize the WIVT, the average change in sensitivity was found to be -0.0071 counts/cm H_2O·day with sensors having an average drift -0.81 cm H_2O over 1.5 hours. Many research papers document sensor errors during use, but few papers describe the verification tests used to determine sensor performance characteristics useful in mitigating sensor errors. The methods and findings in characterizing the WIVT will be helpful for not only future development of the WIVT but similarly designed pressure sensors.

Additionally, Chapter 4 introduces the portable base station that is worn on the user to track IAP. The portable base station was compared to the Zarlink application

development kit (ADK) base station, which was developed and optimized by the manufacturer. The data acquisition rate and the signal power were evaluated and found to be similar to the ADK base station. Overall the WRAPS meets design specifications and accurately tracks and stores intra-abdominal pressure measurements outside of the clinical environment.

Chapter 5 examines the IAP during a Pilates Mat and Reformer exercise routine as compared to a threshold activity of sit-to-stand. Methods used to explore IAP measurements were mean peak pressures, area under the curve (AUC), and first moment of area (see Appendix B) [3]. This approach was novel in two ways: 1) IAP during Pilates exercise has yet to be quantified and 2) rather than focusing on monitoring IAP of activities that are restricted, i.e., lifting exercises, the goal of this investigation was to design a low intra-abdominal pressure exercise routine as a way to increase exercise in women that have undergone pelvic floor surgery—a different approach from the current clinical practice [13]–[15]. It was found that on average, no Pilates exercise activity produced peak pressures above sit-to-stand; however, when examining AUC over a threshold of 40 cm H_2O, Pilates roll-up performed on the Mat, and Reformer produced significantly greater IAP than sit-to-stand. By eliminating the roll-up exercise, a low intra-abdominal pressure exercise routine is described, which may be adapted for postsurgical patients.

In vivo testing raises the potential for motion artifacts to influence the measure IAP. Intra-abdominal pressure is produced by a variety of factors including the abdominal muscles, pelvic floor muscles, diaphragm, blood pressure, lymphatic system, and

movement [16], [17]. It is known that the orientation of the sensor varies by a maximum of 2 cm H_2O. This orientation of the sensor will most certainly influence pressure readings of the sensor during performed activities. A benchtop test was conducted in which a sensor was monitored at atmospheric and 70 cm H_2O with and without shaking. Results of this test reveal that moving the senor while pressurized at 70 cm H_2O in the same plan produced a 0.77 cm H_2O increase in sensor amplitude range from resting, while shaking in multiple directions produced a 0.92 cm H_2O increase.

Conducting a motion artifact test in vivo is difficult due to multiple physiologic contributors to IAP. A possible in vivo experiment to test for motion artifact would be to passively move limbs of a participant during supine lying when they are supine lying. However, even passively moving a limb would cause fascia, connective tissue, and muscles connected to the hip to move, which would produce a change in IAP. Additionally the change in leg position would change dynamics of the lymphatic system and blood pressure in the abdomen contributing to IAP.

6.2 Conclusion and Future Direction

The newly developed wireless IVT will be used to monitor IAP during a series of upcoming home-use studies as well as future studies investigating the relationship of IAP and exercise and activities of daily living. Throughout the work presented in this dissertation, the WIVT has tracked IAP during physical activity in 60 women during two exercise sessions in a laboratory environment (see Appendix D), 46 women during exercise in an observed exercise environment (results in progress), and 20 women during

an hour-long Pilates exercise routine.

Methods were described to test and evaluate the accuracy of a newly developed pressure sensor. These tests ensured the WIVT met the TIR:9 1992 and BP:22 1994 standards as well as laid a foundation of performance for future design modifications [11], [12]. Future modifications to the existing design include wireless frequency matching and power optimization to account for signal attenuation due to tissue absorption [18].

Methods were developed to compare IAP between activities. These methods include mean max pressure, area under the curve (AUC), and first moment of area (FMA) [3] (see Appendix C). The current clinical paradigm for the pathology of pelvic floor failure occurs when an event, such as forceful exercise or childbirth, causes stretching or tearing of pelvic floor muscles, nerves, and connective tissue, which lead to the development of a pelvic floor disorder potentially decades after the initial trauma [19]–[21]. Measuring mean max intra-abdominal pressure allows researchers to quantify the severity of an activity and its potential to overcome the structural limitations of the pelvic floor, leading to damage. Obesity is also considered a factor in the development of PFDs [22]–[25]. In the case of obesity, AUC and FMA might play a larger role in the development of a PFD than peak pressures since the measures are able to describe IAP during prolonged activities or during inactivity. FMA allows further distinction between activities that are short in duration but exhibit high peak versus those that are long in duration with low peak pressures. The measures developed to describe IAP during controlled laboratory and exercise studies will play an important role in future studies where IAPs during daily living activities are tracked. In future studies, study personnel will not be observing participants

as they perform activities, so very little will be known about what a participant will be doing, i.e., what time a lift, carry, or walking occurred. Using previous data acquired in a controlled laboratory environment, pattern recognition may be used such that researchers can determine what activity the individual was performing by recognizing the various waveforms using mean max, AUC, and FMA measurements.

This research has led to the development of a low intra-abdominal pressure exercise routine that can be used by postsurgical patients to maintain physical activity. By providing clinicians with an alternative to restrictions, women can lead healthier lives and perhaps recover faster and more completely. This exercise routine is the first of its kind for minimizing IAP. This may provide the basis for which other exercise routines can be compared to give women wider alternatives for exercise. Future studies can utilize the Pilates exercise routine to track postsurgical outcomes to determine if the exercise routine plays a role in rehabilitation or tissue repair as these data do not currently exist [15].

The greatest unanswered question with this investigational research is how activities and increased IAP can contribute to the progression, recurrence, and incidence of PFD. Using technology and methods developed in this dissertation it is conceivable that a next step in realizing how IAP relates to pelvic floor health is to monitor women's IAP during daily living and developing improved methods of assessing the onset and progression of pelvic floor disorders. Longer term data collection and analysis may provide some answers to what type of IAP profile affects pelvic floor health. Once a healthy pelvic floor loading profile is understood, women can be prescribed the exercise

routine to best improve their pelvic floor health. A personalized medical solution can also be envisioned where women are assigned a WIVT to take home to monitor their IAP during a week-long duration. Results captured during this week would then be evaluated with clinicians or bioengineers to determine how activities performed could be modified, excluded, or added to in order to increase pelvic floor health.

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APPENDIX A

A GEL FILLED INTRAVAGINAL TRANSDUCER FOR EXTENDED MEASUREMENTS OF INTRA-ABDOMINAL PRESSURE

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A Gel Filled Intravaginal Transducer for Extended Measurements of Intra-abdominal Pressure

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***Abstract*— Limitations of the standard urogynecological pressure transducers have not adequately provided reliable measurements of intra-abdominal pressure (IAP) during physical activities. A previous novel intravaginal pressure transducer (IVT) was developed in order to overcome the shortcomings in existing technology. The design of the IVT was validated though comparisons with existing pressure transducers in both the clinical and bench top settings. However, a number of improvements were needed to overcome limitations in the previous design. A larger elastomeric capsule with transducer was developed and filled with silicone gel to replace the existing saline filled capsule and to better integrate proposed wireless technology. Impulse response and frequency testing were compared between the saline filled IVT and the new gel filled sensor and were found to be equivalent. Additional testing was performed on the gel filled device including drift and temperature measurements of sensitivity and offset. Results show the temperature coefficient of offset and sensitivity within correctible limitations with our proposed signal conditioner circuits.**

I. Introduction

THE pelvic diaphragm or pelvic floor is composed of a network of muscles and other tissues that assist in supporting the pelvic organs including the vagina, rectum, uterus and bladder. A number of problems can arise from the dysfunction of the pelvic floor including a range of problems from urinary incontinence to loss of bowel control. Pelvic floor disorders among women are becoming increasingly prevalent. Studies indicate that one in every nine women will have surgery to repair dysfunction in the pelvic floor. Out of these surgeries, almost 29% return for surgical revision [1]. Proper healing post operatively is vital for the successful outcome of surgery yet, these muscles are constantly subjected to intra-abdominal forces due to daily physical exertion. The relationship between daily activity and pelvic floor loading has yet to be defined because current methods are incapable of gathering "real-world" data.

Intra-abdominal pressure (IAP) is directly related to the forces on the pelvic floor. The measurement of IAP is accomplished by the use of two primary devices: sensor-tipped catheters and fluid-coupled transducers.

Sensor-tipped catheters monitor pressure using the distal end of the catheter which allows placement of the sensor directly on the source of physiological pressure. This type of sensor monitors dynamic pressures more accurately than fluid-coupled devices due to their more direct form of measurement. However, the accuracy of the sensor-tipped catheters is dictated by the placement and orientation of the sensor and is therefore highly directional dependent [2].

In contrast to sensor-tipped catheters, fluid coupled systems measure the pressure externally using an incompressible fluid to couple the sensor to the physiologic source of measurement. The fluid-filled tube conveying the pressure signal can have an effect on the measurement accuracy and fidelity as the signal traverses the tubing from the physiologic source to the sensor [3]. Dampening and resonance effects in these systems depend on factors such as the length, diameter and stiffness of the tubing. Furthermore, any air bubbles in these systems can also alter the transducer response. Fluid-coupled systems have evolved to include open-ended catheter and balloon catheter systems. Open ended catheters must couple the physiologic environment with the use of liquid or gas. Balloon catheters transmit pressure by the displacement of partially filled balloon and can be used in a non-fluid environment such as the vagina or rectum.

In a clinical setting the IAP is measured using both fluid coupled and sensor tipped transducers in three primary locations: rectum, bladder and upper vagina depending on the instrument used. This being the case, different transducer types do not produce identical responses during routine urodynamic studies [3]. This disparity is likely due to the

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limitations and inherent differences of each transducer system. Most sensor-tipped IAP measurements record pressures via the rectum or the vagina. However, these compartments are not liquid or gas filled and are not a closed system and therefore can lead to erroneous readings when the sensor-tip is in the wrong location or pressed up against the tissue wall. Occasionally these sensor tipped catheters are placed in the bladder. Again, the placement and orientation of the sensor will drastically change the readings. This technique is not popular for longer term measurements due to infection as well as comfort [4]. Finally, balloon catheter fluid-coupled systems used in the vagina can be favorable for static IAP measurement but their poor dynamic response often leads to imprecise measurements during physical activity.

Current transducers described do not allow the accurate measurement of IAP during daily physical exertion. Elevated abdominal pressure during physical activity has been known to lead to pelvic organ prolapse, urinary incontinence and abdominal hernias but there is a discrepancy among clinicians and researchers as to which activates truly increase IAP to an undesirable level [5].

The previous design of a novel intra-vaginal transducer (IVT) consisted of a microsensor and supporting electronic components within a capsule that was placed in the upper vagina for pressure monitoring. These prototypes consisted of a bullet shaped capsule made of a silicone elastomer modeled after a tampon (Figure 1). The electronic component consisted of a piezoresistive pressure sensor die mircobonded to a custom printed circuit board. An aluminum ring was fitted around the circuit board allowing the circuit to be coated with silicone gel, protecting the electronic wiring. Next the PCB was set into the capsule and sealed using silicone elastomer. A syringe filled with saline was used to fill the capsule, serving as the transfer medium from external forces applied to the capsule to that on the sensor [6].

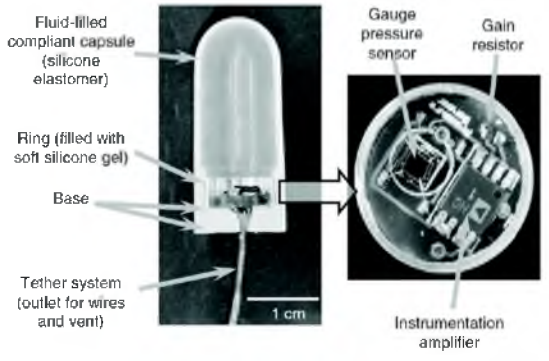

Fig. 1. Previous design of the IVT. The current design replaces the saline filled elastomeric capsule with silicone gel. Instrumental amplifier was not used for experiments[6].

Bench top and clinical testing of the previous design showed an improved dynamic response of the IVT over the conventional fluid-coupled balloon catheters in the both the impulse response and swept sine wave tests. During pilot clinical trails, the results of bench testing confirmed the improved dynamic response of the IVT over the rectal transducer [6]. However, there were some limitations with the design of the IVT. Some of the shortcomings included the potential for electrical failure with use of saline, inability to store the saline filled device and the limited mobility associate with a wired device.

The new generation of IAP sensors replaces saline filled capsule with silicone gel. This improvement achieves a longer shelf life by eliminating the loss of water due to high moisture vapor transmission rates across the semi-porous elastomeric capsule as well as eliminating ionic migration to the electrical components. The silicone gel allows the device to be easily sterilized rather than injecting the device with saline prior to use. This replacement also eliminates the possibility of a short circuits and open circuits due to saline induced corrosion. To accommodate the circuitry needed to implement wireless telemetry, an increased size was required. The future project goal is to integrate wireless capability, eliminating the use of wires while achieving IAP monitoring for a period of one week.

II. Methods

A bullet shape capsule design was continued from the previous design due to the comfort and familiarity with menstruation hygienic devices. The final size and dimensions were 1.59 centimeters in diameter and 3.48 centimeters in length with a hemispherical distal terminus. Molds were designed to maximize repeatability and fabricated out of aluminum. Capsules were molded from silicone elastomer (Nusil, 45 Shore A) and cured at 150 °C for 30 minutes.

A piezoresistive pressure sensor die was mounted over a predrilled hole on the custom PCB and attached using a uv-cure adhesive. The sensor was electronically linked to the PCB by the use of a mirobonded wire. The microwires were then coated in a uv-cure silicone to protect the wire bonds while creating airtight pressure seal between the circuit board and the sensor. The wired circuit board was then placed in an elastomeric capsule pre-filled with silicone gel (Nusil, Med12-6300 mixed 3:2 part A to B). The gel with the circuit board was cured at 100°C for 15 hours. Next a 40cm long vent tube was placed inside a pre-drilled hole in the circuit board, making contact with the bottom side of the sensor. The vent tube was secured using a uv-cure adhesive creating an airtight seal. The vent tube allows all measurements to be referenced to atmospheric pressure. Two coin cell batteries (Energizer, 186) were linked in series and bonded to wires from the circuit board. The remaining space in the capsule was then filled and cured with silicone elastomer completing the assembly.

A pressure chamber was built to test the sensitivity, linearity and frequency response of the IVT. The chamber was pressurized to 421 cmH_2O (41.36 kPa) using a NIST

traceable reference transducer (Testcom, ER3000) and the output and excitation voltage were recorded using a data acquisition instrument (Agilent 34970A). Results of the test were fitted with a linear regression. The resonance of the IVT was tested by sealing the IVT and reference transducer in a water filled chamber. A pressure generator (Millar, WGA-200) was linked to a electromagnetic pressure converter (Millar, 429) was attached to the top of the chamber creating an air tight seal. The pressure generator was connected to a waveform generator (Agilent, 33220A) programmed to generate a sine wave ranging in frequency from 0 to 30 Hz over 15 seconds. An impulse response test was carried out using the same experimental setup described above. The waveform generator was programmed to deliver a square wave at frequency of 1Hz.

Four sensors were maintained at room temperature for 20 minutes then were elevated to a temperature of 37 °C for 48 hours. Sensor offset was measured every 30 seconds to determine temperature coefficient of offset. The drift testing of the gel-filled sensors was accomplished by monitoring the voltage excitation and output of the sensors when elevated to 421 cmH_2O (41.36 kPa) in the pressure chamber. Every seventh day the sensors were again pressurized and output was recorded to determine changes in baseline drift and sensitivity. The test was conducted for 4 weeks while immersed in a saline solution at room temperature.

III. Results

The silicone gel that was chosen was Nusil Med12-6300 a medical grade material designed to provide accurate pressure transmission and response. Linearity and sensitivity tests were conducted on gel filled devices using Med12-6300 varying the mixture of part A and part B. The mixtures tested were 1:1, 1:3 and 2:3 parts A:B respectively. It was found that these mixtures made no statistical difference in the performance of the sensor (data not shown). The final mixture chosen for all subsequent testing was 2:3 parts A to B due to curing temperatures and length of time in the oven.

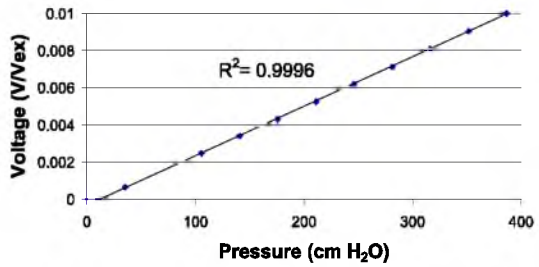

Fig. 2. Calibration curve for the intravaginal transducer

The intravaginal sensor exhibited a linear response (R^2=0.9998) from 0 to 421 cmH_2O (Figure 2). The sensor exhibited no resonance characteristics when compared to the previous intra-vaginal transducer (Figure 3). Likewise, the dynamic response test showed little difference from the previous design (Figure 4).

Temperature drift results show an increase in the voltage output of these sensors likely due to the thermal expansion of the silicone gel (Table 1). The coefficient of offset and sensitivity was calculated for the drift testing (Table 1).

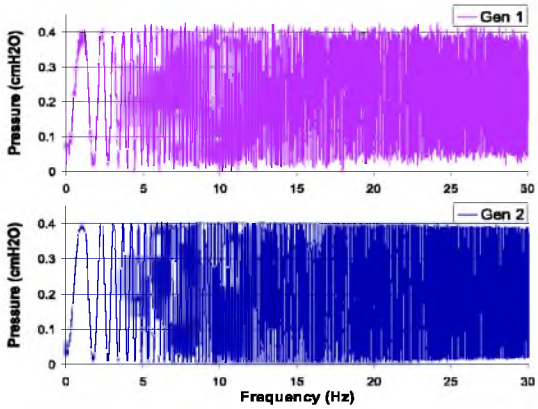

Fig 3. Swept sine wave frequency plot for the first and second generation IVT

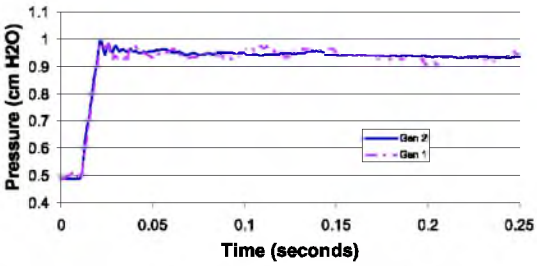

Fig. 4. Response of first and second generation transducers during an impulse

TABLE I
OFFSET AND SENSITIVITY CHANGES

Quantity	Percentage	cm H_2O
Change in Offset 25°C	11.2	34.2
Change in Sensitivity 25°C	2.1	n/a
Temperature Coefficient of Offset (25-37°C)	8.8	9.8

The change in offset and sensitivity at 25°C are the averages of values obtained during the long term drift test (n=3). Temperature coefficient of offset reflects the average change of the output voltage at 37°C from the values at 25°C (n=3)

IV. Discussion

We compared the performance of a gel filled IVT for use in urogynecological studies to the previously validated saline filled design. The shape and package of the IVT was found to be comfortable for patients and is radially symmetric allowing pressure measurements independent of direction

within a non-fluid filled tissue compartment. The device was found to have high linearity with no measureable overshoot or resonance effects when compared to saline filled IVT. Based on the bench top results, the gel filled design is suitable to move forward into the wireless development phase of the project.

The temperature coefficient of offset (TCO) is the measured offset voltage due to the temperature change from room temperature to 37°C or body temperature. Measured TCO values were found to be within the range of correctable values using the ZMD signal processor chip (ZMDI, ZMD31014). Furthermore, the change in sensitivity due to temperature was also found to be within correctible limits. Possible corrections could include the use of individual sensor characterization for drift and offset using established manufacturing techniques.

Future direction of the study will be the integration of sensor conditioning and wireless technology into the IVT device. This integration will be leveraged through a circuit design that takes advantage of three key components: a ZMD 31014, TI MSP 430F2013 and Zarlink 70101 MICS transceiver. The ZMD contains a front-end amplifier, 14 bit ADC and serial conversion with SPI interface. The microcontroller will handle all executive functions and control both the signal conditioning and transceiver. The wireless signal will be received by an external data logger that is carried by the person. Data will be time stamped with event markers for later analysis by clinicians.

The gel filled transducer overcomes limitations of the previously reported saline-filled device including ionic migration, sterilization, and longer shelf life. In addition, it exhibits similar frequency and impulse response, has low drift and is within correction limits for TCO and TCS. This next generation design will serve as the design platform for an integrated wireless system that will record intra-abdominal pressure continuously in women for a period of 7 days undergoing activities of daily living and thus provide needed data to better understand the incidence, progression and recurrence of pelvic floor disorders. This data will provide clinicians with an accurate clinical data set to formulate an appropriate activity level that promotes healing after pelvic floor surgery.

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APPENDIX B

CLINICAL EVALUATION OF A WIRELESS INTRA-VAGINAL

PRESSURE TRANSDUCER

Springer and International Urogynecology Journal, vol 23, no. 12, pp. 1741–1747, Clinical evaluation of a wireless intra-vaginal pressure transducer, Y. Hsu, T.J. Coleman, R.W. Hitchcock, K. Heintz, J.M. Shaw, I.E. Nygaard, and is given to the publication in which the material was originally published with kind permission from Springer Science and Business Media.

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ORIGINAL ARTICLE

Clinical evaluation of a wireless intra-vaginal pressure transducer

Yvonne Hsu · Tanner J. Coleman · Robert W. Hitchcock · Kristina Heintz · Janet M. Shaw · Ingrid E. Nygaard

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Abstract
Objective To describe the development, feasibility and validity of a wireless intra-vaginal pressure transducer (IVT) which can be used to measure intra-abdominal pressure in real-world settings.
Study design A feasibility study was conducted in sixteen physically active women to determine retention and comfort of various IVT prototype designs during activity. A criterion validity study was conducted among women undergoing urodynamic testing to determine the accuracy of the IVT prototypes when compared to accepted clinical standards.
Results A final prototype wireless IVT was developed after four design revisions of the second generation model. The feasibility study found that women reported the final prototype comfortable to wear and easily retained during physical activity. Intra-abdominal pressure measurements from the final prototype IVT compared favorably to standard urodynamic transducers, thus confirming evidence of its utility.
Conclusion We have successfully advanced the design of a wireless, intra-vaginal pressure transducer which provides accurate measures of intra-abdominal pressure. The final wireless IVT is better tolerated by patients and overcomes limitations of traditional urodynamic testing while laying the foundations for intra-abdominal pressure monitoring outside of the clinic environment.

Keywords Wireless intravaginal pressure transducer · Intra-abdominal pressure · Pelvic organ prolapse

Yvonne Hsu is a consultant for American Medical Systems. Robert Hitchcock is a shareholder in Catheter Connections, Inc and a consultant to Navigen Inc.

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Introduction

A popular belief supported by scant clinical data is that strenuous physical activity and the associated load from increased intra-abdominal pressure (IAP) on the pelvic floor leads to pelvic floor disorders (PFD) such as pelvic organ prolapse and urinary incontinence [1, 2]. Due to the assumed relationship between IAP and activity, clinicians often recommend drastic long-term activity restrictions for women with existing PFD or after surgical repair [3]. Studying the potential association between IAP and PFDs has been hampered by our inability to measure IAP in real-world settings.

Our group has previously reported on a prototype intra-vaginal transducer (IVT) which correlated well with IAP readings from traditional rectal balloons, yet had less measurement error and noise [4]. It had fewer design limitations compared to both the fluid-coupled rectal transducers and the micro-tip bladder transducers [5]. However, this proof of principal device lacked user mobility, electronic durability

and an extended shelf life. It could be used only in a laboratory setting and women were limited in mobility as it was connected by cables to the data monitoring device. The overarching aim of our research is to develop a wireless remote abdominal pressure sensor ("WRAPS") which can then be used to measure IAP in various real-world settings. The aim of the current study is to describe the development, feasibility and validity of the second generation wireless intra-vaginal pressure transducer (IVT).

Materials and methods

Similar to the first generation intravaginal pressure transducer (IVT), the second generation IVT was also designed to be placed and retained in the upper one third of the vagina, but needed to house additional circuitry to transmit wireless signals. Additional components needed to achieve wireless telemetry included a signal conditioner, microcontroller, battery, and supporting radio telemetry components. The electronic package was sealed in a gel filled elastomeric capsule which transfers externally applied pressures to the sensor. During the development process, multiple revisions to the capsule design were tested to maximize user comfort, retention during activity, and accuracy of IAP measurement.

In the development process of the wireless IVT, a wired second generation IVT was built for testing. This wired second generation device was an important transition step to the development of the wireless IVT because it allowed the design team to make substantive design changes to the capsule and gel while developing the wireless capabilities in parallel. The wireless IVT circuitry was subsequently developed and evaluated. A detailed description of the engineering processes, components and circuitry used in developing the second generation wireless IVT has been previously described [6].

To test the retention of the varying capsule shapes and sizes, mock prototypes were built. The mock devices consisted of a gel filled capsule with a plastic or aluminum cylindrical tube inside to mimic the rigidity of the proposed electronic package. For device removal, a length of nylon string was tied to the cylindrical tube and sealed in place with silicone elastomer. The devices were cleaned with isopropanol and sterilized with ethylene oxide prior to use. Study approval was granted from the University of Utah Institutional Review Board and informed consent was obtained from volunteers.

Clinical testing proceeded in two phases. The first phase was a feasibility study in which healthy, physically active women reported on the comfort and retention of the various mock prototype devices during exercise and other strenuous activity. The second phase was a criterion validity study in which all prototype IVT pressure measurements were compared to results obtained during standard urodynamic testing. The criterion validity study was conducted in women who were scheduled for urodynamic testing but who did not have evidence of pelvic organ prolapse

We established three acceptance criteria for our device: 1. the device had to be retained during physical activity 2. the subjects had to feel comfortable wearing the device and 3. the device had to measure and record pressure changes in accordance with predetermined specifications. A difficulty for device testing is the lack of a true gold standard for the measurement of intra-abdominal pressure [7]. Urodynamics is one accepted clinical gold standard however standardization is difficult to achieve uniformly [8]. This is especially a problem for determination of "true" baseline since urodynamics baselines are often obtained with adjustments to the device and transducer during the set-up for the study. However, the response of the device to changes of pressure can be compared between our device and urodynamic measurements to establish criterion validity since this is not dependent on baseline. A less than 5 % change from the ideal was determined to be valid. Although no specific clinical accuracy standards exist for urodynamic pressure measurements this 5 % change was selected by our team as a subjective comparison benchmark. As described previously, the wired and wireless IVT's are bench tested and calibrated using NIST traceable standards and meet or exceed the overarching AAMI standard for physiologic pressure transducers which includes accuracy [5, 6, 9].

Women were included in the feasibility study if they were ≥21 years of age, were regularly engaged in strenuous physical activity and provided negative responses to questions about pelvic organ prolapse on the Pelvic Floor Distress Inventory [10]. Women were excluded if they were pregnant, within 6 months postpartum, or had a history of pelvic or vaginal surgery other than hysterectomy. Eligible participants were not menstruating when they completed feasibility study procedures.

Height, weight, age, parity, history of hysterectomy and the Pelvic Organ Prolapse Quantification (POP-Q) [11] measurements were recorded for participants in the feasibility study. Women were given simple, pictorial instructions for the insertion and removal of the device. They were instructed to insert the IVT into the top of the vagina and requested to wear the device during strenuous physical activity or exercise. Common activities women performed while wearing the IVT prototype included running, climbing, and aerobics. They reported on the ease of device insertion and removal, comfort, and whether the device was retained during activity.

For the criterion validity study, wired and wireless IVT devices were built to evaluate device performance against a standard urodynamic rectal balloon catheter. Pressure sensors were calibrated to 350 cm H_2O using a National Institute of

Standards and Technology (NIST) traceable reference transducer, cleaned with isopropanol, and sterilized using ethylene oxide prior to human use.

The criterion validity study was conducted in women undergoing standard urodynamic testing as part of routine clinical care. Women were included if they were ≥21 years of age and were not currently menstruating. Women with a history of pelvic or vaginal surgery other than hysterectomy, or who were pregnant were excluded. Women were also excluded if they had prolapse of the apical, anterior or posterior compartment beyond the hymen.

After uroflowmetry, the urodynamics nurse placed a LifeTech #6 French water-filled catheter into the bladder along with a Laborie #10 French balloon catheter into the rectum past the internal anal sphincter to measure IAP. The rectal balloon catheter was filled with 5 ml of sterile saline and both catheters were then connected per standard practice to a cystometry machine (Aquarious, Laborie Medical Technologies). The wired IVT was connected to a DAQ card (NI USB-6211, National Instruments) that was controlled by a laptop running a custom LabView 8.0 program. Pressure readings at zero (atmospheric) were recorded for 30 seconds prior to insertion. The IVT data was captured at a frequency of 120 Hz. A member of the clinical research team then inserted the IVT into the vagina. Routine filling cystometry testing then progressed in which the rectal and bladder catheters were zeroed to atmospheric pressure. Discrepancies between the rectal and urethral pressure was corrected in the usual fashion by either flushing or repositioning the catheters. The IVT was not adjusted to correct for discrepant pressures during setup; rather, this adjustment was made post hoc (Fig. 3). Bladder and rectal measurements were collected at 15 Hz with standard clinical cystometry software (Laborie Medical Technologies). At a bladder volume of 200 ml, each participant performed a series of seated cough and Valsalva maneuvers followed by a series of standing coughs and Valsalva maneuvers. The relative changes in pressure of both the rectal balloon catheter and the IVT were plotted and compared.

Each version of the second generation wired IVT was tested. This included 3 capsule versions of the second generation wired IVT. The final version (revision 4) was used as the design for the wireless IVT.

This final version of the IVT design was found to be retained, was comfortable and had criterion validity. The wireless components were then built into the final version of the IVT (Fig. 1). Wireless urodynamic comparisons were collected from additional volunteers undergoing standard urodynamic testing using this final version. The standard urodynamic testing protocol was followed as described above. The wireless IVT was programmed to sample at 30 Hz and transmitted data packets to a base station (ZLE70101BADA Applications Development Kit, Zarlink) every 1.5 seconds. Prior to the study an atmospheric measurement was taken by sampling the pressure of the device for 30 seconds. The changes in pressure recorded during Valsalva and coughs of both the rectal balloon catheter and the wireless IVT were plotted and compared. Correlation coefficients and percentage change from ideal were calculated. An ideal 1:1 curve with slope equal to 1 was used to signify the best case scenario in which all relative peak pressure changes from the wireless IVT was also recorded by the rectal balloon catheter. Percent change in measurement between the rectal balloon catheter and the IVT was calculated by plotting a straight line though the data while setting the intercept of the line equal to zero. A plot was generated relating the slope of the line to the percent error in measurement from the ideal 1:1 curve. A seventh order polynomial was used to fit the relationship between the slope and the percentage error from the ideal graph. Using

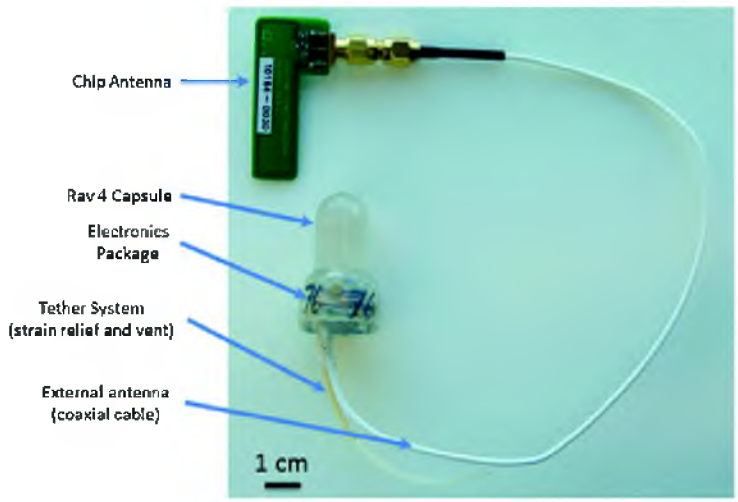

Fig. 1 Picture of a wireless generation 2 Rev 4 IVT. The electronics package is sealed in a gel-filled Rev 4 elastomeric capsule. An external antenna with a chip antenna is used to transmit wireless data packets to the base station receiver. The tether system allows for easy removal of the IVT after use

the seventh order polynomial, percent error was then calculated based upon the slope of each data set.

Results

Feasibility study

16 women with a mean age of 41 years (range 24 to 61 years) were enrolled in the retention study. The mean parity of enrolled women was 1.5 (range 0–4), and average body mass index was 24.6 kg/m^2 (range 17.1-29.7 kg/m^2). Two participants had undergone hysterectomy. Pertinent mean (range) POP-Q points (available for 14 of 16 participants) were: TVL 9 (range 8 to 11), Ba −0.86 (range −2 to 1), Bp −1.36 (range −3 to 1) and C −5.93 (range −7 to −3). Some study participants tried multiple IVT devices.

Revision 1

The original wired prototype (first generation wired IVT) was packaged in the revision 1 capsule (Table 1 Rev 1) which was modeled after female hygienic devices. While this device performed well in terms of comfort, retention and accuracy, we needed to modify the dimensions to incorporate wireless components. We ultimately developed three subsequent capsule designs to accommodate the new components while maintaining retention and comfort.

Revision 2

The initial modification to the original design was an increase in the capsule size to accommodate the wireless electronics (Table 1 Rev 2). While accurate when tested in the laboratory (described further below), it was not retained during activity by any of the four women in whom it was tested.

Revision 3

The design was further modified by shortening the overall length and increasing diameter, in order to improve retention (Table 1 Rev 3). Retention with the revision 3 design was improved; five of seven women retained the device during activity. However, revision 3 proved inaccurate in subsequent urodynamics comparisons (described further below).

Revision 4

This was a modified hybrid of the revision 2 and revision 3 designs (Table 1 Rev 4). Five of five women retained revision 4 device during activity. It also had good criterion validity in the urodynamics laboratory.

Participants described revision 1, 2, 3 and 4 as easy to insert and comfortable to wear. Only revision 3 was noted as difficult to remove (Table 1).

Criterion validity study

The wired devices (revisions 2–4), were tested against the conventional urodynamics balloon catheter placed in the rectum. Before use, each wired IVT was calibrated in a pressure chamber in the range of 0–350 cmH_2O. The revision 2 IVT correlated well (r=0.98) with rectal catheter data with an error of 0.1 % (Fig. 2) but subsequent retention studies failed (Table 1). In contrast, the revision 3 IVT also measured a high correlation coefficient (r=0.94) but measured a lower relative change in abdominal pressure than the

Table 1 Feasibity study report

Capsule	Dimensions Length/Diameter	Retention	Prior Hysterectomy	Insertion of the device was easy?	Device was comfortable to wear?	Removal of the device was easy?
Rev 1 	27.4 mm/12.7 mm	Retained in 3 out of 4 subjects. Retention considered success	1/4	3 Strongly Agree 1 Agree	1 Strongly Agree 2 Agree 1 Neutral	2 Strongly Agree 2 Agree
Rev 2 	35.6 mm/15.9 mm	Failed retention on 4 of 4 subjects. Retention considered failure	0/4	4 Strongly Agree	4 Strongly Agree	2 Strongly Agree 2 Agree
Rev 3 	27.9 mm/23.8 mm	Retained in 5 out of 7 subjects. Retention considered success	1/7	3 Strongly Agree 4 Agree	3 Strongly Agree 4 Agree	1 Strongly Agree 3 Agree 2 Disagree 1 Strongly Disagree
Rev 4 	37.3 mm/23.8mm 15.9mm	Retained in 6 out of 6 subjects. Retention considered success	1/6	6 Strongly Agree	6 Strongly Agree	3 Strongly Agree 3 Agree

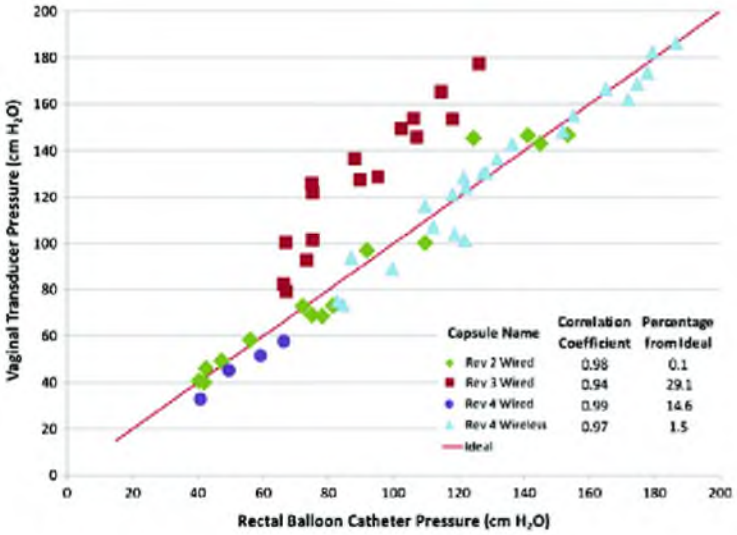

Fig. 2 Combined correlation of peak pressures with the analog and wireless IVT compared to the rectal balloon catheter during coughing and Valsalva maneuvers as part of a standard urodynamics test. The ideal line shown above indicates the ideal case in which the rectal and the intra-vaginal transducer report the same IAP. Percent from ideal measurements were based upon the slope of the best fit line through the data points compared to the ideal line

conventional balloon catheter contributing to the 29.1 % error. The revision 4 wired IVT pressure changes correlated well (r=0.99) with peak pressures measured by the rectal catheter and had an error of 14.6 %.

After evaluating the retention and criterion validity results, the revision 4 design was selected to move forward as the best candidate design for wireless integration. Once developed, these wireless revision 4 designs were also compared to the conventional urodynamics balloon catheter placed in the rectum. The wireless device with the revision 4 capsule correlated well for changes in pressures with the rectal balloon catheter (r=0.97) with a low error of 1.5 % compared to the ideal 1:1 line. Examples of relative pressure changes obtained with the device compared to the rectal balloon during coughing and Valsalva maneuvers are shown in Fig. 3. The baselines between the analog and wireless Rev4 design and the rectal balloon ranged in error between 1.3 % to 46.7 % or 0.2 cmH_2O-17.3 cmH_2O.

Discussion

We successfully developed a wireless version of an intravaginal pressure sensor. This required close collaboration between the engineering and clinical teams. The clinicians were initially disappointed that we would be unable to use the shape and dimensions of the revision 1 prototype because this had been well tolerated in our earlier work [4]. The main engineering factor driving the size increase was the size of the Zarlink Wireless chip. Unfortunately, the Revision 2 device failed the retention study likely because the diameter did not allow it to be maintained in the upper third of the vagina. While the final Revision 4 IVT is longer and wider, all participants in the retention study found it to be comfortable, easy to insert and easy to remove.

In developing versions 3 and 4 of the IVT, we considered dimensions of various sources, including various menstrual tampons, Colpexin sphere pessaries [12], and vaginal measurements. When Revision 2, to our surprise, could not be retained,

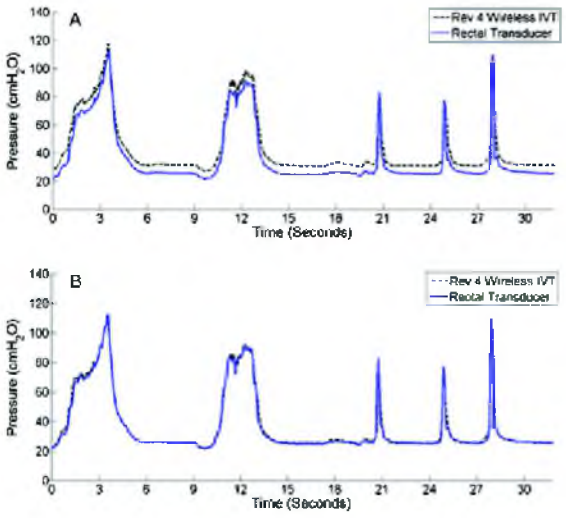

Fig. 3 Pressure tracings of Rev4 wireless IVT and rectal transducer of both recorded pressures (**A**) and pressure tracings with baselines adjusted to match (**B**)

we brought a simulation pelvic model and modeling clay into our multi-disciplinary design meeting and the engineers, urogynecologists and exercise scientists brainstormed about various possibilities using the clay models. While the engineers had seen many figures and photographs of pelvic anatomy, the simulation model was very helpful for them to understand the vaginal axis, position of cervix, posterior fornix, etc. We emphasized that the final model had to be easy for the woman to insert herself and had to be positioned in the upper vagina.

In addition to the wireless technology and changes in dimension, other improvements made to the first generation IVT include the integration of a silicone gel as well as changes made to the capsule which increased the tensile strength and tear strength properties as well as increased the durability of the wireless IVT. These modifications advance the IVT towards a design capable of tracking IAP associated with daily activities outside of the laboratory environment.

In existing studies of intra-abdominal pressure, investigations have focused on measuring how certain activities increase intra-abdominal pressure in a urodynamic setting with the goal of determining activity restrictions in the post-operative period. While there is a great deal of variability, pelvic surgeons often recommend significant restrictions in exercise and lifting post-operatively. Even one year after surgery, women who had undergone abdominal sacrocolpopexy cited physician advice as a reason for interference for physical activity [3]. Although there are limited data, surgeons make these recommendations for a plausible reason. By limiting activities that increase intra-abdominal pressure, they hope to decrease failure as a result of excess loading on the pelvic floor. However, investigators have found that lifting from certain positions do not increase intra-abdominal pressure substantially [13] and that many unavoidable or uncontrolled physiologic functions such as coughing and Valsalva are associated with increases in intra-abdominal pressure in access of activities that patients are warned about [14, 15].

The posterior vaginal vault is an accepted location for measuring IAP and results between rectal and vaginal IAP measurements are comparable [16]. However the same report acknowledges that these measurements require careful setup and continuous surveillance and adjustment of the measurement devices to obtain quality recordings. In addition to setup, subject position can play a large role in abdominal pressure and in the correlation between rectal and vaginal IAP measurements [16–19]. Absolute comparisons between rectal and vaginal IAP measurements are dependent on multiple factors including subject, transducer type, transducer setup and measurement technique [16, 20]. Given these vagaries, we considered the International continence Society (ICS) criteria for ensuring quality control of pressure recordings: 1) resting values for Pabd, Pves and Pdet are in a typical range, 2) the Pabd and Pves signals have only minor variations caused by breathing or talking and should be similar for both signals 3) coughs ensure that Pabd and Pves respond equally [16]. When we applied these recommendations to the wireless IVT, we determined that the wireless IVT provides quality IAP despite any bias or offset between the rectal and vaginal measurements.

The primary limitation of the current device is that it cannot be used in women with significant apical prolapse as it will likely fall out. For our feasibility study, we required that women have no symptom of a bulge. While we did not exclude women based on POP-Q results, none of our participants had more than Stage II prolapse. In addition, our wireless version currently requires a base station that is not easily portable to acquire data. Therefore, we are still limited to exploring IAPs during activities that can be done in the same room as the base station. We are now in the process of designing wearable base stations that will be the size of a pager and able to store wireless IAP measurements for the device to be truly portable.

Lastly, we were not able to determine the accuracy of our device in measuring absolute pressures since there is not a clinical gold standard for measurement of intra-abdominal pressures. Therefore, we are not able to determine if differences in baseline measurements between our devices and the rectal balloon are due to differences in device function, accuracy or location.

We are currently conducting a test-retest reproducibility study of the wireless second generation device in the exercise laboratory setting during a variety of activities. The final wireless remote abdominal pressure system (WRAPS) can then be used for long term measurements of IAP during real world activities. Such a tool, until now lacking in our research armamentarium, will allow exploration of the association between IAP, activities and pelvic floor disorders.

We have successfully advanced the design of a wireless vaginal pressure transducer which allows accurate measures of intra-abdominal pressure directly in the vagina. This is better tolerated and overcomes limitations in traditional urodynamic measures of intrabdominal pressure. Compared to a previous wired design, we are closer to measuring the role that physical activity plays in incidence, progression and reoccurrence of pelvic floor disorders.

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Conflicts of interest None

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APPENDIX C

MORE COMPLICATED THAN IT LOOKS: THE VAGARIES OF CALCULATING INTRA-ABDOMINAL PRESSURE

Adapted with permission from *J Strength Cond Res*, N.M. Hamad, J.M. Shaw, I.E. Nygaard, T.J. Coleman, Y. Hsu, M. Egger, R.W. Hitchcock. pp. 3204–3215, Nov. 2013

METHODOLOGICAL REPORT

More Complicated Than it Looks: The Vagaries of Calculating Intra-Abdominal Pressure

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Abstract

Hamad, NM, Shaw, JM, Nygaard, IE, Coleman, TJ, Hsu, Y, Egger, M, and Hitchcock, RW. More complicated than it looks: the vagaries of calculating intra-abdominal pressure. *J Strength Cond Res* 27(11): 3204–3215, 2013—Activities thought to induce high intra-abdominal pressure (IAP), such as lifting weights, are restricted in women with pelvic floor disorders. Standardized procedures to assess IAP during activity are lacking and typically only focus on maximal IAP variably defined. Our intent in this methods article is to establish the best strategies for calculating maximal IAP and to add area under the curve and first moment of the area as potentially useful measures in understanding biologic effects of IAP. Thirteen women completed a range of activities while wearing an intravaginal pressure transducer. We first analyzed various strategies heuristically using data from 3 women. The measure that seemed to best represent maximal IAP was an average of the 3, 5, or 10 highest values, depending on activity, determined using a top-down approach, with peaks at least 1 second apart using algorithms written for Matlab computer software, we then compared this strategy with others commonly reported in the literature quantitatively using data from 10 additional volunteers. Maximal IAP calculated using the top-down approach differed for some, but not all, activities compared with the single highest peak or to averaging all peaks. We also calculated area under the curve, which allows for a time component, and first moment of the area, which maintains the time component while weighing pressure amplitude. We validated methods of assessing IAP using computer-generated sine waves. We offer standardized methods for assessing maximal area under the curve and first moment of the area for IAP to improve future reporting and application of this clinically relevant measure in exercise science.

Key Words maximal intra-abdominal pressure, area under the curve, standardized IAP, moment of area, data analysis, waveform analysis

Introduction

Pelvic floor disorders (PFDs), such as pelvic organ prolapse, urinary and fecal incontinence, affect 1 in 4 women (20). Despite the high prevalence, the relationship between PFDs and a woman's activity level, especially as it pertains to exercise or heavy occupational work, remains unclear (2). Clinicians often recommend activity restrictions for women with existing PFDs or after surgical repair for PFD (21), which is performed on 1 in 9 women in the United States (22). A popular belief supported by virtually no clinical data is that there is a correlation between strenuous activities, intra-abdominal pressure (IAP), and PFDs. However, some activities commonly prohibited after surgery (such as lifting more than 10 pounds) seem to raise the abdominal pressure far less than unavoidable activities, like getting out of a chair (10,27). Given the health benefits of physical activity, there is a clear need to understand the relationship between IAP, physical activity, and PFDs. Due to recently developed IAP monitoring systems, the study of this relationship is now more feasible.

IAP can be measured directly or indirectly. Direct IAP measurements are obtained by placing a catheter into the peritoneal cavity (for example, during laparoscopy). This type of invasive measurement is obviously not warranted for measuring IAP during physical activity studies. This leaves indirect measurement as the method of choice for IAP measurements in healthy active women. Indirect measurements can be taken from the bladder, vagina, rectum, and upper gastrointestinal tract and have been shown to accurately measure IAP, although pressures measured from each location reflects characteristics of the local environment (for example, smooth muscle pressure) and IAP (7, 16, 23).

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In exercise settings, IAP has been measured to better understand how changes in IAP affect or are affected by spinal biomechanics (8,9,13), the use of weight-lifting belts (12) and various exercise routines (11). Many exercise studies use a nasogastric manometer or rectal manometer coupled to the associative data collection instrumentation to measure pressure. The use of these types of measurement methods is uncomfortable and limits the types of activities the participants can perform. The data acquisition instruments used for these studies typically require the subjects to be tethered by a cable to a piece of laboratory equipment. In addition, the use of fluid coupled balloon manometric devices–those typically used for gastric and rectal measurements–has been shown previously by our group to suffer from poor dynamic response (17).

We have reported previously on a wireless intravaginal transducer (IVT) for continuous IAP measurement (6,14). These devices are well tolerated by the users and provide a continuous stream of data that accurately reflects IAP during numerous activities including resistance exercises. The continuous and varied nature of the data coupled with a 32 Hz sampling rate requires custom software to process and evaluate the data. In the process of developing the software, we came to realize that no standard exists for calculating measures of IAP. The literature generally notes simply that maximal IAP was measured (4,15) or that an average of the single highest pressure corresponding with a number of trials was used to determine maximal IAP (10,11,19,27), but descriptions of how these values were determined or from what baseline they were calculated were generally not provided (4,8,13,15). This variability is reflected in wide-reported maximal IAP ranges; for example, mean maximal IAP during jumping was reported as 75, 127, 177, and 233 cmH_20 in 4 different studies that used different sensors and sensor locations (4,9,11,27).

Thus, it is difficult to compare and utilize these values to guide clinician-based activity restrictions. Problems that we encountered were not only the number of peaks chosen, but also from what baseline pressures were calculated, i.e. atmospheric or some type of positional baseline. Many reports described recalibrating sensors to zero when pressures were either not optimal or changed with body position. Some designated a single position, supine, as the point where the device is "zeroed", others recorded a baseline, before activity, from which to calculate a net IAP while yet others recalibrated before each activity (4,11,12,19,27). Meanwhile some studies do not indicate which baseline was used or calibration position (9,10). Because of this ambiguity in IAP research, we feel it is necessary to provide a basic standard for calculating reported IAPs.

Clinicians have historically been concerned with activities that result in high IAP (4,10,25,27), yet constant levels of relatively low IAP or brief excursions into higher pressure strata may also result in deleterious stress and strain on the pelvic floor. This question may be addressed by considering the pressure–time function rather than isolated measures of pressure amplitude. A standard approach for these types of IAP measurements does not exist. Prior reports have measured area under the curve (AUC) (1) for IAP; however, they neither include measurement details sufficient for the development of custom software programs nor incorporate a wide variety of activities (1,11).

As we worked to develop a standardized, nonsubjective, computerized approach to analyze IAP, we realized that guidelines were lacking and that various issues were more complex than we had anticipated. For example, simply choosing the single highest peak to describe maximal IAP was often not representative of the overall range of highest peaks during a specific activity. In addition, no consistent quantitative method has been previously described to determine IAPs from a large data set. Over the course of 12 meetings, our research group of exercise scientists, bioengineers, urogynecology clinicians, and statisticians carefully considered various options that could be used to describe IAP maximums and AUC during different types of activities. We also analyzed the pressure waveforms for the first moment of the area (FMA), a measure that includes both pressure and time but places additional measurement emphasis on pressure amplitude. Our main goal was to apply a computerized method to detect maximal IAP values in pressure waveforms where there are tremendous variations in pressure profiles depending on subject and type of activity. In a broader sense, this work describes the development and validation of a method to capture maximal amplitudes of IAP signals that is less vulnerable to measurement error because it decreases the bias from any single error in peak measurement.

Methods

Experimental Approach to the Problem

To be consistent with existing literature and because upper vaginal pressure correlates well with IAP, we refer throughout to "IAP", thought the reader should note that we actually measure upper vaginal pressure. We also use the term "maximal IAP" to be consistent with the literature but note that more correct term for our method of calculating IAP would be "mean net IAP", that is, the difference between maximal pressures and minimal pressures during a specific activity.

Our group visually, in 3 women, and quantitatively, in an additional 10 women, examined pressure tracings collected during subject activity sessions to best determine how to approach and calculate meaningful IAP measures. We considered many tactics for determining maximal IAP based on actual data tracings from the activity sessions (see Methods for Assessing Maximal IAP). The software algorithm we developed for calculating maximal IAP was compared with the single highest peak method and to the mean of all peaks method in a given pressure tracing to evaluate whether a clinically significant difference exists between these methods. To further assess the pressure waveform and to account for the influence of time, measurements of AUC and FMA were calculated. The accuracy of the maximal IAP, AUC, and FMA algorithms were finally validated using computer-generated sine waves.

Subjects

Thirteen healthy women aged 20–43 years (mean ± S.D: 29.2 ± 8.1 years) who were not diagnosed with pelvic organ prolapse and who self-reported regular involvement in strenuous physical activity provided written informed consent before engaging in this study. All study procedures were approved by the University of Utah Institutional Review Board.

Procedures

Laboratory Protocol. Subjects completed a series of activities as described by a laboratory protocol which was designed to include a variety of activities that women may perform on a routine basis or in exercise settings. The activities were limited to those that could be reproduced in an exercise laboratory setting. Activity sessions were completed on days when subjects were not menstruating and that were convenient to subjects and included morning, afternoon, and evening times. All activity sessions were done in the same temperature-controlled indoor laboratory. Although the protocol was not excessively demanding, we recommended women not to eat 1 hour before the protocol and to report to the laboratory well hydrated. Additionally, subjects were instructed to void their bladder before inserting the IVT. Data collection occurred during June through December 2011.

Pressure values were measured using a newly developed wireless IVT whose design specifications and testing results have been previously described (5,6,14,17). In brief, this system includes a pressure sensor sealed inside a gel-filled capsule that looks much like a tampon, a tether made of flexible polymer tubing that provides an atmospheric pressure reference and allows for IVT removal, and an antenna for communicating pressure data wirelessly to a base station. Atmospheric pressure readings were obtained for 30 seconds before the IVT being inserted by the subject.

Participants performed 27 activities that fall into 3 following categories: general exercise, routine activity, and those commonly done during urodynamics, a test of bladder function. Activities were performed in a laboratory equipped with a Quinton Q-Stress TM55 treadmill (Bothell, WA, USA), a Monark 28E cycle ergometer (Vansbro, Sweden), exercise dumb bells, an 8 inch exercise step, and a variety of household items for lifting and carrying activities. General exercise activities included walking with varying speed and grade, running, seated and standing cycling, stepping, shoulder press, various trunk exercises (full sit-ups, abdominal crunches, side-bridge, modified superman), push-ups, stretches (quadriceps, hamstring, and low back), and jumping. Routine activities included walking with an 11.3-kg sack on one hip to simulate carrying a child, lifting and carrying 13–18 kg objects, scrubbing the floor, dusting, and stand to sit. Coughing and Valsalva maneuver (abdominal straining) were included as they are standard in urodynamic studies (18,23). Most activities in the laboratory protocol required 20–40 seconds to complete. The order of laboratory activities was consistent with a standard exercise protocol that involved gradual warm-up progressing to higher intensity activities (walking, running, cycling), followed by easier tasks to reduce heart rate (stepping, stand to sit), lifting and carrying tasks, and ended with stretching. The only exceptions to the trend above were Valsalva maneuver and jumping. These tasks were placed at the end of the protocol in the event they resulted in displacement of the sensor, which would have interrupted natural flow of the protocol.

Pressure Data

Each sensor was calibrated in the laboratory using a National Institute of Standards and Technology traceable reference transducer from 0 to 350 cmH_2O and programmed with a unique identifier to prevent cross-talk with other wireless IVT devices. Pressure units of cmH_2O are used because they are standard for IAP assessment in urogynecology studies. Before the study, sensors were sterilized and preheated to body temperature (37°C) to minimize temperature-induced offset of the sensor from room to body temperature. IAP pressure measurements were obtained at a frequency of 32 Hz with a wireless data packet being sent to the base station every 1.5 seconds. Each wireless packet contains header information including pressure values with associated time

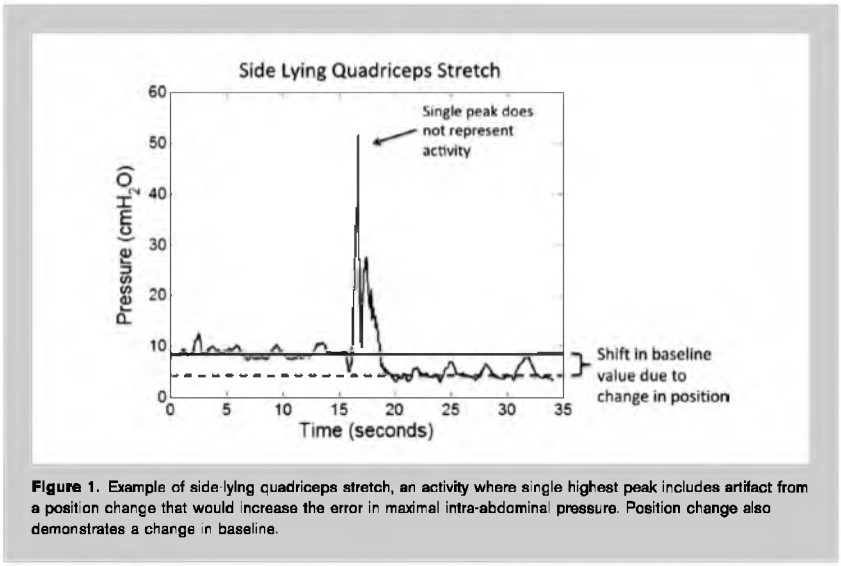

Figure 1. Example of side-lying quadriceps stretch, an activity where single highest peak includes artifact from a position change that would increase the error in maximal intra-abdominal pressure. Position change also demonstrates a change in baseline.

stamps, temperature, and internal battery status. Data are managed by a custom Graphical User Interface (GUI) program that allows the user to monitor the values of the sensor in real time. The output of the GUI is a structured text file. The text file is read by data converter software and subsequently converts the raw pressure count output of the wireless IVT based upon the calibration profile of the sensor. Pressure tracings for each baseline and activity were generated.

Methods for Assessing Maximal Intra-Abdominal Pressure

Maximal IAP should be representative of the highest pressures observed for any given routine or exercise activity in the laboratory protocol without bias from any single error in peak measurement. Our research group identified various possible means for identifying maximal IAP. One requirement was to sample as much pressure data from any given activity as possible to reduce the impact of potential measurement error due to one aberrant measurement; thus, we dismissed the strategy of assessing the single highest peak, despite its previous use in the literature (10,12,19,27). We illustrate an example of a problem with the single-peak method of assessing maximal IAP in Figure 1. To identify the most robust means, we began by visually inspecting the pressure tracings from 6 subject trials collected from 3 subjects who completed the protocol twice. Because of the variety of pressure tracings from the activities, we looked for patterns in the data. Some tracings from dynamic activities with repetitive motion such as walking, running, standing, cycling, and shoulder press yielded somewhat predictable patterns. In these tracings, the highest pressure values, which we label as peaks, were easy to visualize. However, to determine maximal IAP for the entire segment of data, the timing, height, range, and number of peak values for any activity needed to be considered. These values varied even in the more predictable pattern activities. In some activities, there were multiple upward inflections contained in one peak, which a computer software program would recognize as separate, individual peaks. Therefore, we imposed a timing rule, such that peaks must be at least 1 second apart to reduce sampling bias (Figure 2). In addition, several activities have peaks that are 1 second apart but are considerably lower in magnitude than others. A computer software program would necessarily include these in a calculation of mean maximal IAP if all peaks during a period were averaged. We defined these as "peaklets" and did not wish to include these in our calculation of maximal IAP (Figure 3).

From this visual inspection, we then developed 5 following initial strategies for capturing maximal IAP: (a) average of 3 highest peaks, (b) average of 10 highest peaks, (c) average of all peaks, (d) average of peaks above a 75% threshold, and (e) average of peaks above a 50% threshold. The average of 3 highest peaks strategy was based on previous methodology (11,27). For all measures, we added the caveat that included peaks must be separated by at least 1 second. Similar to the 3-peak strategy, the 10-peak strategy first required identifying the 10 highest peaks

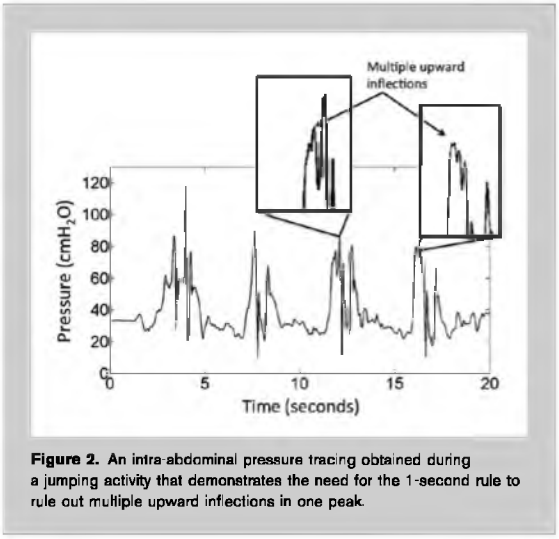

Figure 2. An intra-abdominal pressure tracing obtained during a jumping activity that demonstrates the need for the 1-second rule to rule out multiple upward inflections in one peak.

greater than 1 second apart, from which a mean value was calculated.

We also considered calculating maximal IAP based on a percentage of the range of pressure values in any given tracing, in contrast to calculations based on a predetermined number of peaks. The calculated percentage of the range is added to a previously reported positional pressure to determine a threshold, and only peaks above this threshold are evaluated. In 2 separate strategies, 75% or 50% of the calculated range between the highest and lowest pressure values are added to the positional pressure, and a mean maximal IAP is calculated by averaging all peaks at least 1 second apart above this threshold.

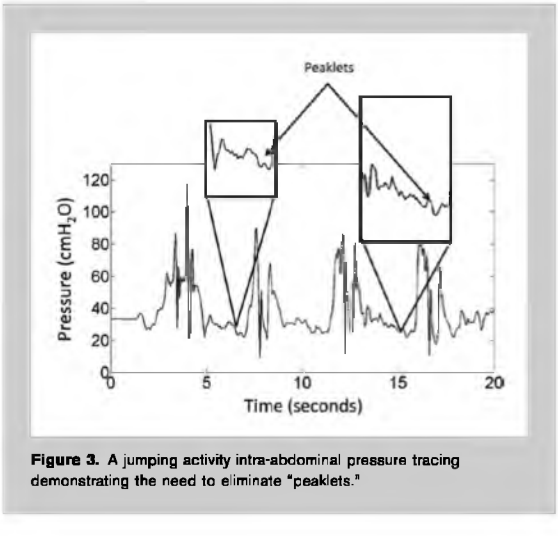

Figure 3. A jumping activity intra-abdominal pressure tracing demonstrating the need to eliminate "peaklets."

Evaluating Strategies to Determine Maximal Intra-Abdominal Pressure

We visually analyzed tracings for all activities in the laboratory protocol using the initial 3 subjects to determine how well each strategy captured maximal IAP (Figure 4). The 3-peak strategy was a good fit for 2 activities, but not a good representation for others that had multiple peaks over the course of the activity (Figures 4 A, B). The average of all peaks did not reflect maximal peaks well because the software recognized "peaklets" or fluctuations in IAP, as peaks. This strategy was a marginally good fit for 2 activities (Figure 4C) but a poor fit for most others (Figure 4D). The 10-peak strategy was a good fit for 11 activity groups, such as running and levels of walking and cycling, providing a consistent representation of maximal IAP but did not work well for the most physically demanding activities in our protocol, such as heavy lifting (Figure 4E). Sometimes, the assessment of IAP was limited by a subject's ability to perform the activity for the entire time segment allotted, and 10 peaks were not clearly identifiable (Figure 4F). Furthermore, some activities required the subject to perform a particular activity a set number of times at increasing intensities. For example, dumb bell shoulder press consisted of 3 sets of 8 repetitions using progressively greater weight for each set. In this activity, the number of peaks that represented maximal IAP was limited to the number of repetitions completed per subject.

In both the 75% and 50% threshold strategies, the calculation of maximal IAP depended on 2 factors that varied for each activity and subject; the range of pressure in any given segment and the positional pressure. If the range of pressures was large, such as in stepping, and the lowest pressures were below the positional pressure, the calculation

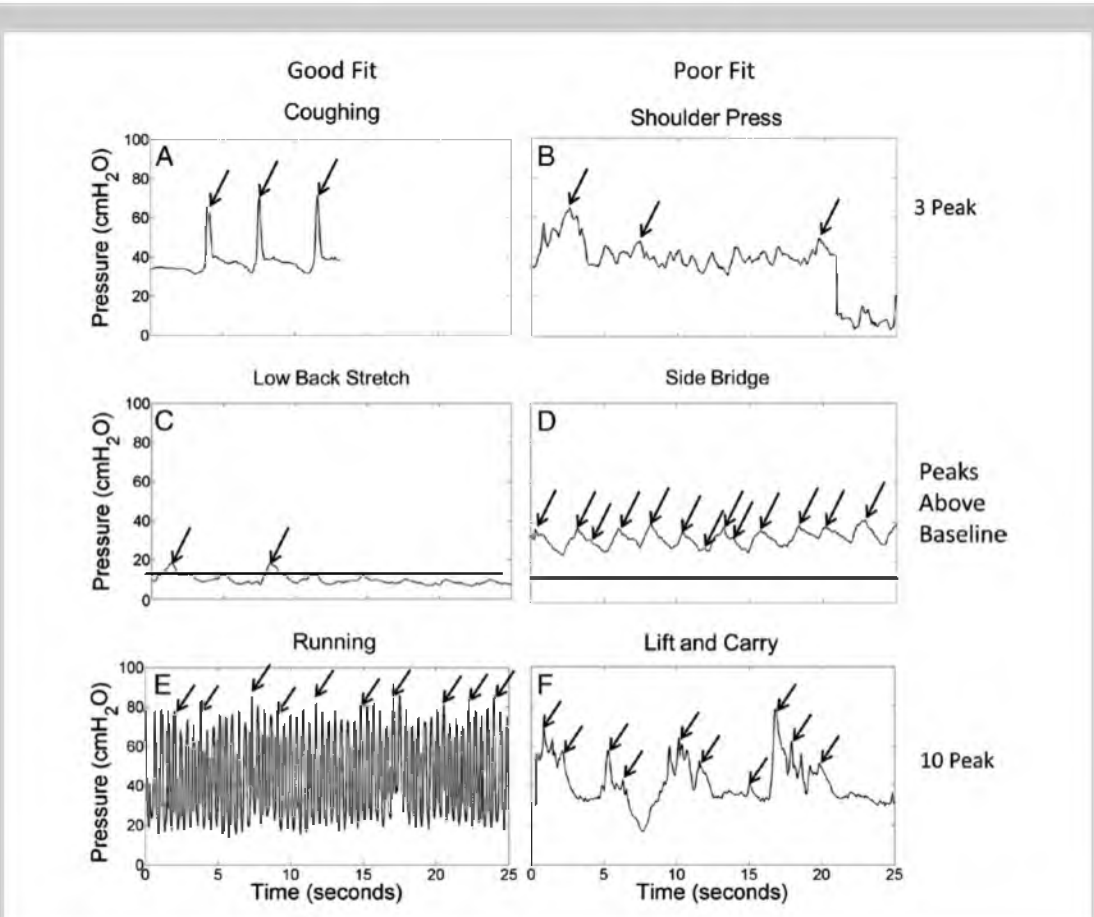

Figure 4. Representation of intra-abdominal pressure (IAP) tracings and appropriateness of some of the strategies tested to determine maximal IAP for the following: 3-peak strategy (A) (B); Peaks above baseline strategy (C) (D); and 10-peak strategy (E) (F). Peaks selected in each rule are demonstrated by arrows. In the 3-peak and 10-peak cases, the software is programmed to select the highest peak, followed by the next highest peak at least 1 second apart, followed by the next highest peak, etc.

of maximal IAP was nearly impossible because very few or no peaks were identified above the predetermined threshold (Figure 5A). Alternatively, if an activity had a relatively narrow range of pressures such as side bridge, and the lowest pressures were above positional pressure, then almost all of the peaks in the tracing would be included in the calculation of maximal IAP (Figure 5B). The 75% threshold strategy was a good fit for only 3 of the 14 general activity groups (Figure 5C). The 50% threshold strategy was also highly variable. It often included too many peaklets (Figure 5D). It was a good fit for 3 activities and a poor fit for 14 of the activity groups. Overall, the use of a threshold did not seem to be a good strategy for determining maximal IAP.

Based on our preliminary visual analysis of methods to determine maximal IAP, we chose 3-peak and 10-peak averages as methods that seemed to consistently reflect maximal IAP. However, in applying these strategies to additional activity tracings, we realized that an additional group was needed to analyze certain activities that consistently produce only a mid-range of peaks (i.e. 4–9). This was the case for 6 activities, including those that often resulted in premature fatigue by our subjects (i.e. shoulder press, full sit-ups). To accommodate these activities, we added an average of 5 peaks group.

The activities we studied thus fell into the following groups: 3 peaks: coughing and Valsalva maneuver; 5 peaks: lift and carry, curl ups, sit-ups, side bridge, stand to sit, shoulder press (all); and 10 peaks: walking (all), running, slow stepping, cycling (all), erasing the board, scrubbing the floor, superman pushups, jumping, hamstring stretch, low back stretch, and quadriceps stretch. An example of points determined for a 10-peak activity is demonstrated in Figure 6.

A computer program was developed using Matlab software (R2009A, MathWorks; Natick, MA, USA) to discern the highest 3 peaks, highest 5 peaks, and highest 10 peaks at least 1 second apart using a top-down approach; meaning that the software identified the peaks starting with the highest, second highest, and so forth. Collectively, we refer to this approach as the mean top-down approach to calculating maximal IAP.

In addition to positional changes, expected when assessing IAP, we also observed baseline fluctuations during some activities in some women that seemed unrelated to position. This led us to re-evaluate the sensor again in ideal laboratory conditions. We found that the sensitivity of the device does not change a clinically significant extent from initial calibration to after human testing was conducted. The offset of the sensor was found to change daily, and although the offset is

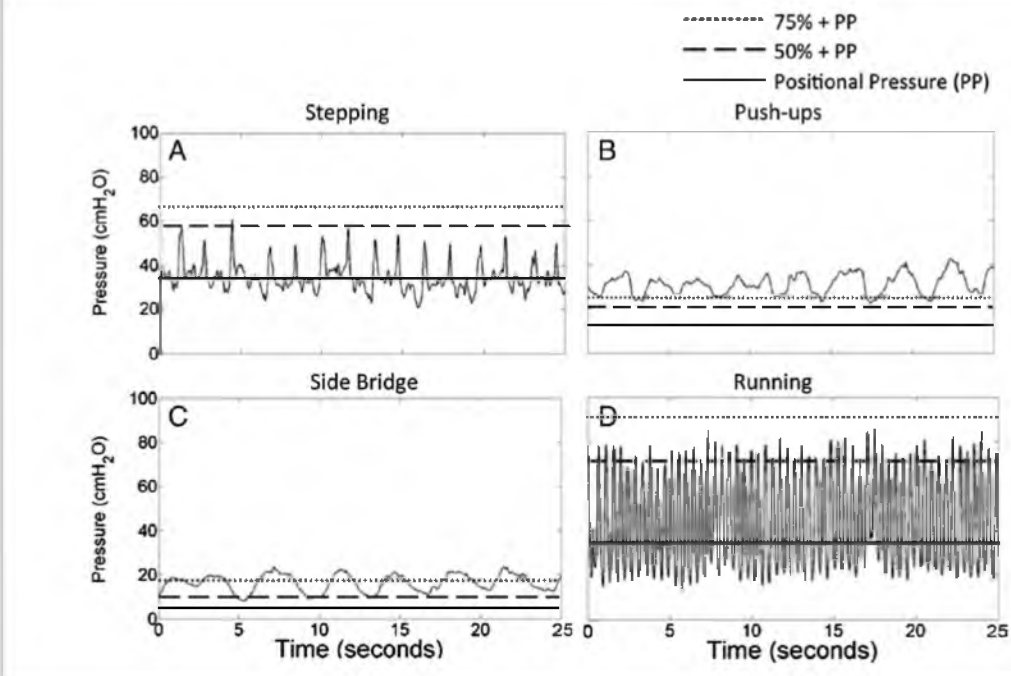

Figure 5. The 75 and 50% strategies applied to 4 different activities: Graphs (A) and (B) demonstrate a poor fit for both the 50% and 75% strategies. Graph (C) demonstrates a good fit for the 75%, but a poor fit for the 50% strategy. Graph (D) demonstrates a good fit for the 50%, but a poor fit for the 75% strategy.

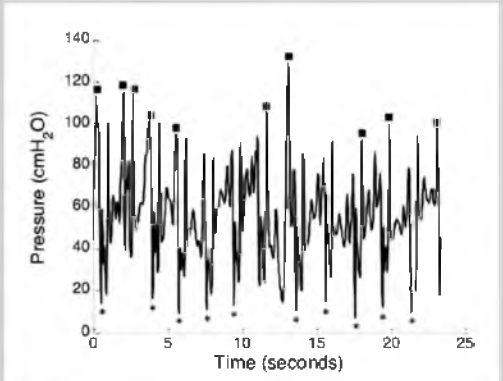

Figure 6. Intra-abdominal pressure tracing for jumping, demonstrating the mean top-down approach for calculating maximal intra-abdominal pressure (IAP). *Represent minima and ■ represent maxima used to determine maximal IAP.

initially set to atmosphere, there still exists an offset from the measured pressure of the wireless device and the true peritoneal IAP. Therefore, confirming accuracy of the sensor itself, we concluded that these fluctuations were due to physiologic changes in the upper vagina (for example, sensor movement, vaginal smooth muscle contraction, small bowel peristalsis, etc.). Rather than arbitrarily recalibrating to zero, as is commonly done in clinical situations, or choosing a preset baseline, we chose to instead report net IAPs as differences between maxima and minima. Minima are obtained similarly to maxima as follows: the 3, 5, or 10 trough pressures are averaged, and the net pressure is a result of the difference between the highest averaged pressures and the averaged low pressures (Figure 6).

Area Under the Curve

Maximal IAP reflects the highest pressures achieved during an activity, but it does not take into consideration the duration of the pressure over time. Clearly, there is a difference in a rapidly increasing and decreasing pressure such as a cough versus a high-pressure activity with longer time duration such as slowly lifting a heavy object. We considered area under the curve, a measure that includes both the pressure amplitude and time (reported as $cmH_2O \cdot s$) to characterize the time associative properties of pressures between activities. However, a simple AUC is limited in that pressure and time are weighted equally and the result does not describe potential amplitude contribution to the overall measure. For example, high-pressure activities over short duration could produce similar AUC results when compared with low-pressure activities over long duration as shown in Figure 7.

Other measures of the pressure waveform over time include higher order moments such as the FMA. The FMA is a finite measure of a small area multiplied by the y-axis component, in this case cmH_2O. Because we are interested in how IAP from various physical activities may strain

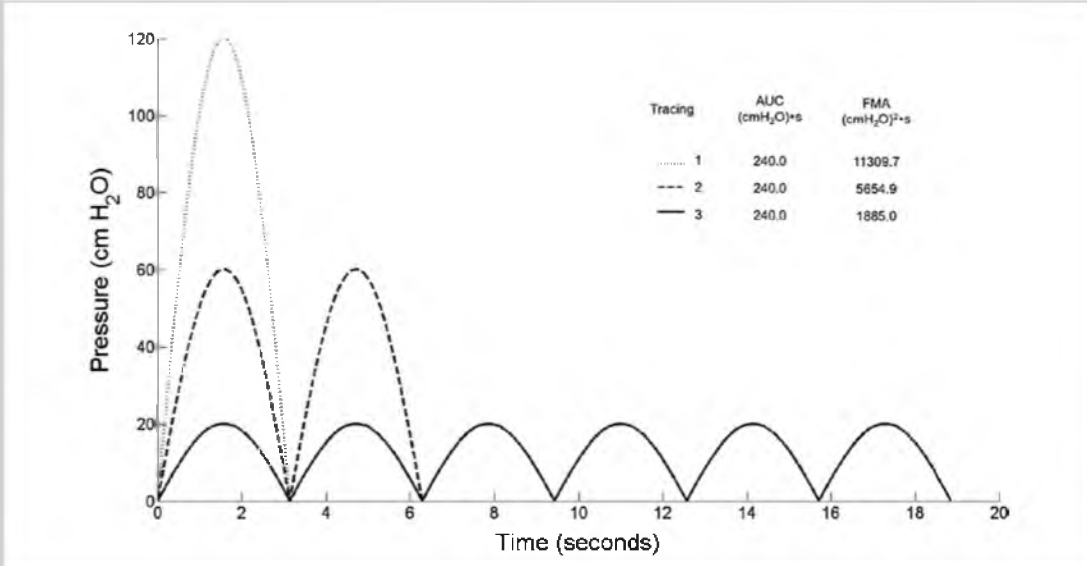

Figure 7. Demonstration of 3 intra-abdominal pressure tracings that each has the same calculated area under the curve 2. While area under the curve (AUC) is the same, first moment of area (FMA) is very different between each of the tracings.

Table 1. IAP by three measurement methods (n = 10).

	Single-peak method (cmH_2O)		Mean top-down method (cmH_2O)		Method of all peaks (cmH_2O)	
n = 10	Sample average	SD	Sample average	SD	Sample average	SD
Cough	125.1	29.0	113.5	28.8	23.3	10.5
Lying valsalva	88.3	33.6	83.3	33.0	34.6	19.0
Stand/sit	41.4	15.7	37.4	14.8	20.8	6.2
8 lb. shoulder press	11.2	4.7	8.9	3.7	4.7	2.1
Walking 3 mph	31.7	6.3	27.0	4.5	19.1	3.3
Running	73.5	17.6	68.5	17.1	54.9	13.0
Seated cycling	12.9	2.3	10.7	2.0	6.2	1.1

IAP = intra-abdominal pressure.

pelvic floor structures, we considered this additional method to distinguish high-pressure/low-duration activities from low-pressure/long-duration activities. These differences are illustrated in Figure 7. Both AUC and FMA will be calculated from the calculated baseline pressure for each individual for each activity.

Analysis

Quantitative Analysis of Maximal Intra-Abdominal Pressure. As noted previously, we used mean net IAP, that is, the difference between maxima and minima, to reflect maximal IAP. We compared the IAP calculated using our mean top-down approach to (a) IAP reported by identifying the single highest peak and (b) IAP calculated using the mean of all peaks in a given pressure tracing, including peaklets. In our comparisons, we used an accuracy range of 5 cmH_2O as a standard, because this magnitude of pressure difference is considered clinically meaningful (23). Using pressure data from 10 additional subjects whose data were not used in the visual inspection described, IAP was calculated using our newly developed software algorithm from the following representative activities as follows: 3 peaks (coughing, Valsalva maneuver), 5 peaks (stand to sit, 3.6-kg seated shoulder press), and 10 peaks (cycling at 2 kilopond meters, walking at 4.8 km per hour and running at 8–9.6 km per hour). To preserve an overall 5% significance level per activity, we used a Bonferroni-corrected 1.7% significance level for tests comparing pairs of methods for a single activity.

We compared the different measurement techniques using 2 different statistical methods. We recognized that these IAP measurement methods are naturally ordered, that is, within a single subject, the maximal IAP as determined by measuring the single highest peak is as high or higher than IAP determined from the mean top-down approach, which, in turn, is as high or higher than the mean IAP of all peaks. Thus, the first analysis utilized 3 one-sided Bonferroni-adjusted *t*-tests to test whether the population average of maximal IAP, as determined by each method, exceeded

Table 2. Statistical equivalence results.

	Single peak method vs. mean top-down approach		Mean top-down approach vs. method of all peaks		Single peak method vs. method of all peaks	
Cough	D	$p = 0.0042$	D	$p < 0.0001$	D	$p < 0.0001$
Lying Valsalva	I	–	D	$p < 0.0001$	D	$p < 0.0001$
Stand to sit	I	–	D	$p = 0.0016$	D	$p = 0.0006$
8 lb shoulder press	E	$p < 0.017$	I	–	I	–
Walking 3.0 mph	I	–	D	$p = 0.0086$	D	$p = 0.0003$
Running	I	–	D	$p = 0.0032$	D	$p = 0.0003$
Seated cycling	E	$p < 0.017$	I	–	D	$p = 0.0030$

D = population average differences exceeding 5 cmH_2O between IAP measurement methods, beyond chance; E = population average equivalence within 5 cmH2O between IAP measurement methods, beyond chance; I = indeterminate: unable to determine from the present study.

Table 3. Peak analysis of generated and activity plots.

	Number of peaks correctly identified	Known maximal IAP (cmH_2O)	Calculated maximal IAP (cmH_2O)	% Difference
Waveform				
Sine Wave 1	3/3	166.5	166.5	0.00%
Sine Wave 2	5/5	166.9	166.9	0.00%
Random number waveform	10/10	146.6	146.6	0.00%
IAP tracing				
Coughing	3	–	54.8	–
Stand to sit	5	–	27.6	–
Running	10	–	63.6	–

IAP = intra-abdominal pressure.

the others by at least 5 cmH_2O. Rejection of the null hypothesis implies that a pair of methods is significantly different by >5 cmH_2O. However, failure to reject the null hypothesis does not prove equivalence. We conducted further equivalence analyses (3) in which 2 methods are considered equivalent if a 2-sided confidence interval on the mean differences between them falls entirely into the interval from 0 to 5 cmH_2O. That is, we would have 98.3% confidence that all the plausible values for the population mean difference between a pair of methods were between 0 and 5 cmH_2O, and an overall 95% confidence that all 3 methods were equivalent, if all 3 confidence intervals comparing methods fell into this specified interval.

Validating Software Algorithm for Intra-Abdominal Pressure Measures

To validate our software algorithm, we generated 3 waveforms with known pressure–time values. These 3 sinusoidal waveforms were analyzed by Matlab software to determine the accuracy at which the software algorithm could detect the highest peaks and calculate AUC and FMA. The equations for these sine waveforms were as follows:

1. Maximal IAP: sine waveform 1) $3x \cdot \sin(3x) + 3x$;
2. AUC: sine waveform 2) $3x \cdot \sin(12x) + 3x$; and
3. FMA: sine waveform 3) $3x \cdot \sin(25x) + 3x$.

Each waveform was analyzed by our custom Matlab program from 0 to 30 seconds in intervals of 0.031 seconds. A random number generated waveform was developed to create another set of artificial pressure data. These data were generated using a random number function in Excel (2010, Microsoft; Redmond, WA, USA) and consisted of 968 data points with each point constrained to a pressure value between 0 and 200 cmH_2O.

Two of the computer-generated sine waveforms (sine waveforms 1 and 2) and the random number generated waveform were used to validate the accuracy of our software algorithm for assessing maximal IAP. The sine waves and random waveform were processed by a custom Matlab program, to determine the 3, 5, and 10 highest peaks for the appropriate tracing. The identified peaks were then compared with the known values for the generated waveforms, and percent error was calculated. These algorithms were considered valid if the calculated maximal pressure was within 2% of the known values for the waveforms.

The 3 computer-generated sine waves were used to validate AUC and FMA. Exact values of AUC (Equation

Table 4. Area under the curve and first moment of area analysis of generated and activity plots.

	Integral AUC $(cmH_2O) \cdot s$	Trapezoidal approximation AUC $(cmH_2O) \cdot s$	% difference	Integral FMA $(cmH_2O)^2 \cdot s$	Trapezoidal FMA $(cmH_2O)^2 \cdot s$	% Difference
Waveform						
Sine Wave 1	1359.79	1359.78	0.00%	61946.0	61944.6	0.00%
Sine Wave 2	1348.04	1348.04	0.00%	60624.2	60624.1	0.00%
Sine Wave 3	1348.49	1348.46	0.00%	60673.6	60668.6	-0.01%
IAP tracing						
Coughing	–	106.9	–	–	1910.0	–
Stand to Sit	–	306.4	–	–	2486.5	–
Running	–	775.8	–	–	16452.0	–

IAP = intra-abdominal pressure; AUC = area under the curve; FMA = first moment of the area.

1.0) and FMA of generated sine waves (Equation 1.1) were calculated by integration. Measurements were validated

$$Area\ Under\ the\ Curve = \int_a^b f(t)dt \approx (b-a)\frac{f(a)+f(b)}{2}$$

$$1st\ Moment = \frac{1}{2}\int_0^{30} (Generated\ sine\ wave)^2\, dx$$

$$1st\ Moment\ approximation = \frac{\frac{.031}{2}\sum_{k=1}^{968}(Pressure_{k+1})^2 + (Pressure_k)^2}{2}$$

using 3 sine waves since integration with the random number data curve is less accurate because there is no defined equation to integrate. The AUC of the computer-generated sine waves was calculated using the trapezoidal approximation in a custom Matlab program. The FMA was determined by the trapezoidal approximation of the square of the pressure in a uniform grid (time interval of .031 seconds) divided by 2 (Equation 1.2).

Due to the constraint of the 0.031-second time interval which limits the resolution of the sine wave analysis, we considered the calculated values of AUC and FMA to be valid if they were within 2% of the known or indicated value. After validating the AUC and FMA calculations, further analyses were carried out on 3 data sets that included coughing, stand to sit, and running profiles.

Results

Quantitative Analysis of Maximal Intra-Abdominal Pressure

Table 1 displays sample averages and SDs of IAP, as calculated by each of the 3 selected IAP measurement methods, for the 7 activities and 10 subjects in the present study. Table 2 compares maximal IAPs (expressed as mean net IAP, or in the case of single peak analyses, as net IAP), as calculated by each of the 3 selected IAP measurement methods in 10 women. As noted, for some activities, IAPs are statistically significantly different between measurement techniques; whereas for others, they are statistically equivalent within 5 $cmH_2O$and for others they are indeterminate (i.e. neither null hypothesis was rejected).

Validating Software Algorithm: Maximal Intra-Abdominal Pressure

Sine waveforms 1 and 2 and a random number data curve were used to compare calculated peak heights as determined by the custom Matlab algorithm to actual values. The Matlab algorithm correctly identified all peaks for the sine waveforms 1 and 2 and random number data curves (Table 3) with 0.00% error. In addition, the custom Matlab algorithm was used to calculate the 3, 5, and 10 maximal peaks on coughing, stand to sit, and running data sets, respectively (Table 3).

Validating Software Algorithms: Area Under the Curve and First Moment of the Area

Sine waveforms 1, 2, and 3 were used to compare AUC and FMA results between known values and the Matlab algorithm. The trapezoidal approximation, a built in function of Matlab, was used to estimate the AUC. This measurement displayed accuracy within 0.00% when compared with results calculated with integration (Table 4). The AUC values were determined for coughing, stand to sit, and running IAP profiles as well (Table 4). The FMA approximations of sine waveforms 1–3 using the Matlab algorithm showed a 0.00%, 0.00%, and (−) 0.01% error from integral values (Table 4). The AUC was calculated for the same 3 activity profiles as shown in Table 3.

Discussion

Assessing IAP during physical activity seems simple but in fact is a challenging undertaking. Results can differ dramatically depending on type of sensor used, position of sensor, how often and when sensor is calibrated to zero, software used for analysis, type of baseline used, and physiological phenomena other than IAP that influence results.

We have developed an appropriate sensor to allow for comfortable, safe, and accurate IAP measurement during a variety of activities and have developed data analysis software to allow computer analysis of large volumes of data. After a successful sensor design and testing phase, our group realized that we also had to overcome the limitations inherent in using software to calculate measures of IAP. After comparing various potential methods used to calculate IAP qualitatively, through visual inspection of data from 3 participants, we conducted quantitative analyses to compare methods in 10 additional women. Based on this evaluation, we chose the mean top-down approach, a strategy that calculates maximal IAP based upon the number of peaks representative of maximal IAP observed during a given activity.

Our results indicate that maximal IAP measured by the mean top-down approach is neither identical to the single peak method nor to the method of all peaks. Within a single subject, these 3 methods produce different-sized measures of IAP as follows: IAP measured as a single peak is always as large or larger than IAP measured by the mean top-down approach, because the single largest peak is averaged with other values to obtain the mean top-down IAP; similarly, IAP measured by the method of all peaks includes as components the values used in the mean top-down approach and is always smallest. Using a 5 cmH_2O difference as one that is clinically significant, we found statistically significant differences by approach in IAPs during some but not all activities. This

requires that a clinical judgment be made in terms of which IAP calculation has best face validity. We believe the mean top-down approach adheres to sound principles of measurement practice, as it does not rely on one value that may represent artifact and it does not include submaximal peaks as does averaging all peaks. No matter the method, for some activities it is difficult to judge how IAP is best measured. For example, in the side-lying quadriceps stretch, IAP is generally low but rises dramatically when the participant changes position to stretch the contralateral leg. We concurred that although change in body position is part of the side-lying quadriceps stretch and should be included in the calculation of IAP, it should not be the sole reflection of the maximal IAP as would be the case in using data from only the single highest peak. In a similar manner, lifting tasks, depending on the relative magnitude of the load, can result in variable IAP peaks by repetitions considering inputs from trunk stabilization and Valsalva. We did not see statistical differences beyond 5 cmH_2O between the calculation of maximal IAP from the single highest peak and the mean top-down approach in the shoulder press task, and in fact these methods were determined statistically equivalent in the second analysis for the same task. Yet, the results may be different in real world application of these methods outside of the laboratory when women are lifting weights on their own terms and in a less controlled environment.

Posttrial bench top testing was performed on sensors to determine accuracy and performance. It was determined that the sensitivity of the device does not change to a clinically significant extent from initial fabrication to after the trials were performed. The offset was found to change daily. The offset is initially set to atmosphere; however, there still exists an offset from the measured pressure of the wireless device and the true peritoneal IAP based on the anatomical influences, location of the sensor, etc. In a previous study, the pressure profiles of a rectal balloon catheter and the wireless IVT were found to be displaced by an offset error (14). In that study, an offset correction was imposed on the wireless IVT to account for this difference, which is synonymous with established urodynamic techniques of adjusting the rectal balloon catheter to establish a baseline. In the present study, no external reference could be used to establish an offset correction because the device is fully positioned with the vagina. Future device development work will center on establishing a reliable offset measurement for baseline activities.

We raised pressure–time analyses as important constructs to consider when describing the potential effect of IAP on the pelvic floor. In the literature, there is little use of AUC as a measure of IAP, and rationale for use is almost nonexistent (1,12). Understanding the potential association between PFDs and strenuous physical activity is grossly hampered by the lack of tools with which to measure and calculate relatively high IAPs during exertion. By assessing several ways to evaluate IAP (maximal pressures, AUC, and FMA measures), in future work, we will be able to determine whether one type of measure best reflects changes in the pelvic floor (e.g. downward displacement of the bladder during activity assessed during ultrasonography). Given the paucity of using AUC to describe IAP in the exercise science and urogynecologic literature, we debated the merits of measuring the entire AUC above atmospheric pressure vs. choosing an arbitrary threshold as a cut-point. There is as yet no IAP cut-point that is known to place women at higher risk for PFDs. Therefore, we measured AUC and FMA from the same average of low-pressure (trough) data points per individual activity and participant.

Understanding the role strenuous activity may play on women's health, both positive and negative, is important. Despite scant data, many physicians currently discourage various types of physical activity in women. The American Urogynecological Society, an organization devoted to the care of women with PFDs, recommends that to prevent PFDs, women should "avoid increased pressure inside the abdomen," "avoid heavy lifting," and "avoid repetitive strenuous activities (26)." In addition to this recommendation to limit strenuous exercise in women are others such as the 2005 statement by International Ski Federation president Gian Franco Kasper, an International Olympic Committee member, who said he didn't think women should ski jump because the sport "seems not to be appropriate for ladies from a medical point of view (24)."

The ultimate goal of our research is to understand whether there are certain types of activities associated with upper ranges of IAP that may, in fact, be deleterious to the pelvic floor, such that women can be appropriately counseled with facts rather than opinions. We have now developed a wireless vaginal pressure sensor (6), herein describe methods for calculating maximal IAP, AUC, and FMA using objective computer software and will next assess the reproducibility of these values in a large sample of women performing a variety of activities. In future work, we will then be able to assess whether women that routinely engage in activities with higher IAP, AUC, or FMA are more or less likely to manifest PFDs or to experience recurrence after treatment.

Practical Applications

IAPs described in the literature to date vary widely during similar activities. Standardizing IAP is essential to understand the primary exposure thought to relate lifting and other physical activity to PFDs in women. To this end, we have developed a novel wireless device that will allow future IAP assessment in women during activities that are not regulated in a laboratory setting. In this article, we present a standardized method for evaluating IAP using computer software and encourage inclusion of AUC and FMA as potentially useful constructs in understanding the impact of physical activity on pelvic floor function. This will enable appropriate recommendations for activity restrictions for women who are predisposed to or have PFDs, without unnecessarily restricting activities that promote health.

Although current sentiment in exercise science suggests that strenuous activity is safe for women, a rigorous approach to understanding IAP associated with lifting and other forms of physical training and sport will further guide evidence-based activity recommendations for women.

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APPENDIX D

INTRA-ABDOMINAL PRESSURES DURING ACTIVITY IN WOMEN USING AN INTRAVAGINAL PRESSURE TRANSDUCER

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Intra-abdominal pressures during activity in women using an intra-vaginal pressure transducer

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Abstract
Strenuous physical activity has been linked to pelvic floor disorders in women. Using a novel wireless intra-vaginal pressure transducer, intra-abdominal pressure was measured during diverse activities in a laboratory. Fifty-seven women performed a prescribed protocol using the intra-vaginal pressure transducer. We calculated maximal, area under the curve and first moment of the area intra-abdominal pressure for each activity. Planned comparisons of pressure were made between levels of walking and cycling and between activities with reported high pressure in the literature. Findings indicate variability in intra-abdominal pressure amongst individuals doing the same activity, especially in activities that required regulation of effort. There were statistically significant differences in maximal pressure between levels of walking, cycling and high pressure activities. Results for area under the curve and first moment of the area were not always consistent with maximal pressure. Coughing had the highest maximal pressure, but had lower area under the curve and first moment of the area compared to most activities. Our data reflect novel findings of maximal, area under the curve and first moment of the area measures of intra-abdominal pressure, which may have clinical relevance for how physical activity relates to pelvic floor dysfunction.

Keywords: *exercise, pelvic floor, strenuous activity, area under the curve, first moment of area*

Introduction

Evidence has emerged to suggest that strenuous physical activity increases the risk for pelvic floor disorders, such as pelvic organ prolapse and urinary incontinence (Chiaffarino et al., 1999; Hendrix et al., 2002; Jørgensen, Hein, & Gyntelberg, 1994; Woodman et al., 2006). There is great need to establish methods to assess this evidence. Defining "strenuous" is for the most part subjective; in the pelvic floor literature, strenuous usually refers to activities that are thought to significantly elevate intra-abdominal pressure (Guttormson, Tschirhart, Boysen, & Martinson, 2008; Nygaard, Hamad, & Shaw, 2013; Weir, Nygaard, Wilken, Brandt, & Janz, 2006). Efforts to measure intra-abdominal pressure during activities have been limited by the need for invasive catheters that must be connected via short tethers to laboratory equipment, as well as by lack of standardisation in defining maximal intra-abdominal pressure. Existing studies that approximate intra-abdominal pressure during certain physical activities by means of vesical, rectal and nasogastric transducers reveal that the range of pressure during specific activities across studies is large, with little concordance in peak intra-abdominal pressures across studies (Nygaard et al., 2013).

To explore the association between physical activity and intra-abdominal pressure, our group developed a novel wireless intra-vaginal pressure transducer to measure intra-abdominal pressure during activities (Coleman et al., 2012). The new intra-vaginal pressure transducer has documented criterion validity (Hsu et al., 2012) and allows for the assessment of diverse activities across a range of intensities and body positions, since the measurement of intra-abdominal pressure is not constrained by wired technology as in previous work (Cobb et al., 2005; Guttormson et al., 2008; Weir et al., 2006).

The most common measurement of intra-abdominal pressure during physical activities found in the

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literature is maximal pressure. Descriptions of how maximal intra-abdominal pressure is calculated vary or are absent from literature to date. We have described standardised methods for assessing maximal pressure during physical activity (Hamad et al., 2013). However, other qualities of intra-abdominal pressure besides maximal pressure may also be relevant to understanding the impact of strenuous activities on conditions such as pelvic floor disorders. Area under the curve reflects both amplitude and duration of pressure but lacks sensitivity in distinguishing long duration/low pressure activities from short duration/high pressure activities. First moment of the area overcomes this limitation of traditional area under the curve measurement by placing greater emphasis on the amplitude of pressure than on duration and is expressed as $cmH_2O^2 \cdot s$. We propose that adding area under the curve and first moment of the area to maximal measurement of intra-abdominal pressure may ultimately further the understanding of links between physical activity and pelvic floor disorders.

The primary aim of this study is to describe maximal, area under the curve, and first moment of the area intra-abdominal pressures obtained using our newly developed, wireless intra-vaginal pressure transducer during a wide variety of common exercise and routine physical activities performed in an exercise science laboratory. Secondary aims are to compare pressure measures between select activities with varying levels of intensity and to compare pressure measures obtained during specific strenuous activities (lifting, sit ups and running) and coughing, as the latter is the standard for eliciting high intra-abdominal pressure in clinical urodynamic studies.

Methods

Participants were 57 women aged 18 to 54 years that reported engaging in vigorous exercise at least three times per week. Women were excluded if they had a positive response to any question on the Physical Activity Readiness Questionnaire (Thomas, Reading, & Shephard, 1992), were currently pregnant, six months post-partum, or had a current injury that would prohibit the completion of the exercise protocol. The University of Utah's Institutional Review Board, which conforms to the declaration of Helsinki, approved study procedures and all participants provided written informed consent.

Assessment of Intra-abdominal pressure

A complete description of the intra-vaginal pressure transducer used in this study as well as evidence for its criterion validity and feasibility of use are detailed elsewhere (Coleman et al., 2012; Hsu et al., 2012). In brief, the intra-vaginal pressure transducer includes a pressure sensor sealed inside a tampon-sized gel-filled capsule, a tether made of flexible polymer tubing that provides an atmospheric pressure reference and also allows for transducer removal, and an antenna for communicating pressure data wirelessly to a base station located in the laboratory.

Laboratory protocol

The exercise protocol was completed in a Human Performance Laboratory at the University of Utah. Participants reported to the laboratory in light exercise clothes. Height and weight were obtained without shoes. After voiding their bladders, women were instructed to insert the transducer into the upper vagina in a manner similar to inserting a tampon. The external antenna was then taped to the abdomen at or slightly above the anterior superior iliac spine.

The standardised activity protocol consisted of 31 activities that included clinical assessments, light, moderate and vigorous intensity exercise tasks and routine household activities. Activity sessions were completed on days when participants were not menstruating and were done in the same temperature controlled indoor laboratory. Each woman completed the exercise protocol on two separate occasions. Although the criterion validity of the intra-vaginal pressure transducer was confirmed in controlled, urogynaecology dynamics testing (Hsu et al., 2012), we were interested in assessing the reproducibility of intra-abdominal pressure as measured by the transducer during this activity protocol (analysis in progress).

Activities were performed in a laboratory equipped with a Quinton Q-Stress TM55 treadmill (Bothell, Washington, USA), a Monark 828E cycle ergometer (Vansbro, Sweden), exercise dumbbells, a 20.3 cm exercise step, and a variety of household items for lifting and carrying activities. Specific activities are shown in Tables I, II and III. Most activities in the laboratory protocol required 20 to 40 s to complete. For clinical assessments and lifting tasks, participants were instructed to do a prescribed number of repetitions. Participants did three repetitions each of coughing and seated and lying Valsalva manoeuvre, modified Superman trunk extension exercise and lifting and carrying tasks. For each level of seated shoulder press, participants were instructed to do eight repetitions and for jumping, each participant jumped in place 10 times. The remaining activities were completed in 30-s time intervals. Each laboratory session required about 1 h to complete. The order of laboratory activities was consistent with a

Table I. Descriptive summary of intra-abdominal pressure (IAP) for urodynamic and aerobic activities.

Activity	N	Range maximal IAP	Median maximal IAP (IQR)	Range AUC	Median AUC (IQR)	Range FMA	Median FMA (IQR)
		CmH_2O		$CmH_2O \cdot s$		$CmH_2O^2 \cdot s$	
Clinical assessments							
Coughing*	53	37.6–199.9	90.5 (72.1–121.5)	51.4–346.6	133 (107.9–190.4)	483.4–16320.6	3298.9 (1908.3–6278)
Lying Valsalva*	57	17.1–176.2	91.3 (67.9–108.8)	420.9–2827.4	1356.7 (1054.6–1768.6)	4190.4–155451.3	46468.2 (28364.2–69875.2)
Seated Valsalva*	57	16.5–207.7	129.3 (106.5–153.2)	680.7–4508	2076.8 (1569.2–2607.3)	3993.7–325274.1	101405.5 (61625.9–143048.3)
Aerobic activities							
Walk 4.8 km · h^{-1}, 0% grade‡	57	15.3–36.6	24.6 (22.5–26.2)	64.1–161.1	99.7 (92.3–115.4)	299–1858.8	679.9 (573.8–893.9)
Walk 4.8 km · h^{-1}, 7% grade‡	57	16.6–50.5	29.3 (26.2–31.8)	69.3–177.6	112.9 (100.5–128.7)	362.9–2582.3	933.9 (743.6–1162.5)
Walk 5.6 km · h^{-1}, 7% Grade ‡	57	20.1–56.1	35 (31.4–39.4)	93–223.1	146.1 (130.6–161.8)	596.9–3552.2	1537.9 (1196.2–1845.9)
Walk 4.3 km · h^{-1}, 0% grade, with 11.4 kg weight ‡	57	12.1–44.3	27 (24.1–30.5)	58.1–195.8	106 (97.4–119.8)	212.2–2638.3	767.9 (654.6–940.7)
Run 8–9.7 km · h^{-1}, 0% grade‡	57	32.4–98.7	66.5 (56–74.1)	116.7–361.4	265.4 (229.2–289.9)	914.1–11224.1	5872.9 (4139.7–7039.9)
Stepping, 20 cm Step‡	57	21.4–48.2	30.4 (25.4–36.1)	69.6–160.9	99.4 (84.1–116.9)	349.7–1764	702.5 (484.8–996.3)
Seated cycling 450 kg · m · min^{-1} ‡	57	4–16.5	8.1 (6.7–9.6)	17.8–69.1	38.1 (31.5–45.3)	21.4–321.8	97.3 (62.9–135.9)
Seated cycling 600 kg · m · min^{-1} ‡	57	5.4–20.6	10.8 (9.4–11.9)	24.9–94.6	49.8 (43.8–54.5)	39.7–584.7	163.6 (121.2–192.8)
Standing cycling 900 kg · m · min^{-1} ‡	57	14.5–66.9	41.6 (34.7–51.7)	64.5–218.1	152.3 (130.2–180.4)	260.2–4216.3	1866.5 (1280.9–2530)

Note: N = number of participants to complete a given activity with adequate data; IAP = intra-abdominal pressure; AUC = Area under the curve, FMA = First moment of the area; IQR = Interquartile range; km·h^{-1} = kilometres per hour; kg·m·min^{-1} = kilogram metres per minute; * = 3 peak activities; † = 5 peak activities; ‡ = 10 peak activities.

Table II. Descriptive summary of intra-abdominal pressure (IAP) for household and lifting activities.

Activity	N	Range maximal IAP	Median maximal IAP (IQR)	Range AUC	Median AUC (IQR)	Range FMA	Median FMA (IQR)
		CmH_2O		$CmH_2O \cdot s$		$CmH_2O^2 \cdot s$	
Household activities							
Erasing board, dusting ‡	57	4.2 – 25.3	9.5 (8 – 12.8)	21.3 – 118.4	43.6 (37.4 – 60.8)	28.5 – 821.8	146 (95.8 – 248)
Scrubbing floor on hands and knees‡	57	5.4 – 58.6	10.2 (8.1 – 13.9)	25 – 253.8	43.9 (35.3 – 57.4)	41.3 – 4297.5	135.7 (87.7 – 236.5)
Stand to sit†	56	20.6 – 99.7	31.9 (28.4 – 39)	87.3 – 342.9	141.3 (123 – 165.2)	467.8 – 11214.2	1254.8 (960.5 – 1728.9)
Lifting tasks							
Lift 13.6 kg, floor to counter and back†	57	17.1 – 62.6	34.5 (28.1 – 41.1)	97.1 – 985.3	361.2 (286.2 – 461.1)	579.5 – 16056.8	3822.3 (2272.2 – 4974.5)
Lift 18.2 kg, floor to counter and back†	57	13.6 – 120	47.9 (37.6 – 59.7)	40.8 – 1426.2	454.5 (371.1 – 621.3)	217.3 – 32320.9	5828.5 (3958.9 – 9091.3)
Seated shoulder press, 3.6 kg†	47	4 – 31.9	8.3 (6.2 – 12.8)	37.4 – 311.5	76.5 (59.7 – 138.5)	44.2 – 1528.2	206.4 (107.8 – 561.9)
Seated shoulder press, 4.5 kg†	48	5.5 – 36.3	11.5 (8.1 – 15.2)	31.3 – 361.5	108.7 (82.9 – 156.9)	45.4 – 3917.7	372.1 (189.9 – 662.5)
Seated shoulder press, 5.5 kg †	41	3.9 – 24.9	10.5 (7.7 – 13.8)	11.5 – 190.2	100.7 (70.9 – 118.7)	17.4 – 1113.2	290.8 (160.6 – 496.8)
Seated shoulder press, 6.8 kg†	12	8.1 – 19.3	10.8 (9.5 – 14.7)	43.8 – 163.3	99 (65.9 – 122)	118.1 – 914.1	319.8 (178.3 – 479.9)
Seated shoulder press, 9.1 kg †	9	10.4 – 36.5	18.8 (13.1 – 30.2)	80 – 292.6	180.9 (90.2 – 208.8)	282.3 – 2569.8	1046.7 (474.4 – 2062.7)

Note: N = number of participants to complete a given activity with adequate data; IAP = intra-abdominal pressure; AUC = Area under the curve, FMA = First moment of the area; IQR = Interquartile range; * = 3 peak activities; † = 5 peak activities; ‡ = 10 peak activities.

Table III. Descriptive summary of intra-abdominal pressure (IAP) for callisthenic and stretching activities.

Activity	N	Range maximal IAP	Median maximal IAP (IQR)	Range AUC	Median AUC (IQR)	Range FMA	Median FMA (IQR)
		CmH_2O		$CmH_2O \cdot s$		$CmH_2O^2 \cdot s$	
Callisthenic activities							
Abdominal curl ups †	57	6.5 – 82.3	18.5 (13.1 – 27.2)	30.5 – 236.2	67 (50.4 – 87.8)	56.8 – 4731.2	321.5 (171.6 – 680.9)
Full sit ups with feet held †	57	13.9 – 128.5	60.4 (48.3 – 77.4)	62.2 – 568.3	263 (226 – 307)	259.7 – 20722.2	4526.6 (3440.4 – 6103.3)
Isometric side bridge †	56	3 – 50.4	15.7 (11.7 – 19.9)	14.2 – 227.7	68.2 (52.8 – 89)	12.9 – 3423.4	308.1 (200.2 – 525.7)
Modified superman‡	56	10 – 45.4	19.9 (14.7 – 27.3)	95.5 – 790.7	286.1 (217.7 – 365.1)	338.5 – 8658.2	1809.4 (1054 – 2983.5)
Push-ups from knees‡	57	4 – 42.5	15.3 (11.2 – 20.3)	19 – 165.2	72.3 (52.1 – 87.8)	36.7 – 2184.9	357.3 (199.6 – 582.9)
Jumping ‡	55	25.7 – 153.9	91.2 (71.8 – 104.8)	242 – 1516.6	627.8 (471.8 – 739.6)	1904.9 – 51125.5	14903.8 (10363.2 – 19703.1)
Stretching activities							
Seated hamstring stretch ‡	57	4.2 – 21.9	9.4 (7.2 – 13.3)	20 – 81	37 (30.4 – 52)	29.4 – 519.3	126.7 (74.4–240.8)
Lower back stretch‡	57	2.5 – 10.4	6 (4.4 – 7.5)	11.6 – 54.4	26.7 (20.3 – 34.3)	9.7 – 231.9	59.5 (30.5 – 99.9)
Side lying quadriceps stretch‡	57	0.6 – 30.4	10.5 (8.1 – 13.1)	2.9 – 126.7	40.6 (32.4 – 49)	0.8 – 1518.3	204.8 (111 – 320.2)

Note: N = number of participants to complete a given activity with adequate data; IAP = intra-abdominal pressure; AUC = Area under the curve, FMA = First moment of the area; IQR = Interquartile range; * = 3 peak activities; † = 5 peak activities; ‡ = 10 peak activities.

standard exercise protocol that involved gradual warm up progressing to higher intensity activities (walking, running, cycling), followed by easier tasks to reduce heart rate (stepping, sit to stand), lifting and carrying tasks, and ended with stretching. However, Valsalva manoeuvre and jumping were placed at the end of the protocol in the event they resulted in displacement of the sensor, which would have interrupted natural flow of the protocol.

In the final 54 participants, we measured intra-abdominal pressure during three pelvic floor muscle contractions (Kegel exercise) in the supine position at the end of the standard exercise protocol. This was done as a quality assurance measure, to ensure that the sensor was in the upper vagina approximating intra-abdominal pressure, and not in the lower vagina, measuring pelvic muscle contraction pressure (Bø & Finckenhagen, 2003; Bø & Sherburn, 2005; Hilde et al., 2013; Hsu et al., 2012). The typical range of pelvic muscle contraction strength in young and middle-aged women is 25 to 50 cmH_2O (though with significant inter-individual variation, with ranges up to 120 cmH_2O) and thus, if pressures generated during pelvic muscle contractions were generally low, it is likely that the transducer is indeed in the upper vagina.

There is no commonly accepted method of defining maximal pressure during activity. We considered many methods, explained in detail elsewhere (Hamad et al., 2013). We chose to measure maximal pressure as a function of the number of peaks that were representative of the highest pressures during activity. Activities were classified as three peak, five peak or ten peak activities (summarised in Tables I–III). We developed a computer program using Matlab software (R2009A, MathWorks; Natick, Massachusetts, USA) to identify peaks and troughs. In the event that a pressure tracing was not of sufficient duration (i.e., the base station did not capture the entire activity segment through wireless transmission) to calculate maximal pressure on the basis of the assigned number of peaks, then the activity segment was considered unanalysable. Maximal pressure from three peak activities was calculated as the mean of the difference between the three highest peaks and the three lowest troughs obtained from the pressure tracing for that activity. Maximal pressure from the five and ten peak activities were similarly calculated, but instead used the five highest and lowest or the ten highest and lowest pressure values. For calculation of area under the curve and first moment of the area, we used the three, five or ten trough average to generate a baseline and then calculated the area under the pressure tracing above that line. For activities that were performed for a 30 s time period, measures of area under the curve and first moment of the area were standardised to reflect 10 s time periods. For activities that were performed for a set number of repetitions, duration was not standardised since this could result in comparing activity segments of differing repetitions.

We chose to calculate pressure measures as the differences between highest and lowest peaks, that is, the net pressure, rather than as the difference between highest peaks and some arbitrary baseline (absolute pressure) because our clinical interest lies in understanding the degree to which certain activities increase intra-abdominal pressure. Additionally, using atmospheric pressure as a baseline reference would reflect resting intra-abdominal pressure for many activities on the lower end of our intensity range.

To describe pressures during these activities, we used data collected during the first exercise session. However, if data for a specific activity segment was incomplete or not able to be obtained, we used data from the second session for that specific activity. Reasons for an incomplete or absent data segment included: (1) participant was physically unable to complete a segment, (2) the sensor fell out of or into the lower vagina, or (3) the base station did not appropriately detect the signals from the sensor.

Data analysis

The sample size was calculated based on the ability to assess the reproducibility of the intra-vaginal pressure transducer. Fifty-six women were determined to be adequate to provide 80% power to provide a 95% confidence interval of width 0.1 for an expected intraclass correlation of 0.8, using Bonett's correction and NQUERY software (Saugus, MA, USA).

We evaluated frequency distributions for each activity. Activities were generally normally distributed, though some were shifted to the right or left. We observed no bimodal distributions. We used descriptive statistics to describe the mean and median net maximal intra-abdominal pressure, area under the curve and first moment of the area. Given the large number of activities, we did not perform across activity comparisons. We selected a priori the following comparisons, which aimed to evaluate pressure differences in similar activities with varying intensities. These included: (1) walking at 4.8 $km \cdot h^{-1}$ on level grade vs walking at 4.8 $km \cdot h^{-1}$ on 7% grade; (2) walking at 4.8 $km \cdot h^{-1}$ on level grade vs walking at 4.3 $km \cdot h^{-1}$ on level grade while carrying 11.4 kg (to mimic carrying a toddler); (3) seated cycling at 450 $kg \cdot m \cdot min^{-1}$ vs moderate intensity seated cycling at 600 $kg \cdot m \cdot min^{-1}$; (4) seated cycling at 600 $kg \cdot m \cdot min^{-1}$ vs standing cycling at 900 $kg \cdot m \cdot min^{-1}$ and (5) coughing, commonly assessed as a high pressure measure in clinical urogynaecology

settings, to each of four activities performed in home or fitness settings that are assumed to have high intra-abdominal pressure: lifting and carrying 18.2 kg, abdominal curl ups, full sit ups, and running. Wilcoxon signed rank tests were used for these eight comparisons. Significance was accepted at $P < .005$ to adjust for multiple tests.

Standing absolute intra-abdominal pressure is known to increase with increases in body mass index (Cobb et al., 2005). To assess whether an association exists between body mass index and net maximal intra-abdominal pressure during a priori specified activities performed in the standing position, we used Spearman rank correlation coefficients to compare body mass index with intra-abdominal pressure for jumping, and lifting and carrying 18.2 kg. Finally, we assessed the correlation between age and intra-abdominal pressure for the same three activities using Spearman rank correlation coefficients. For Spearman correlations significance was accepted at $P < .05$. Wilcoxon signed rank tests and Spearman correlation statistics were run with Matlab Statistics Package (Natick, MA, USA).

Results

We enrolled 60 women. Their mean age was 30.4 years (SD 9.3), mean body mass index 22.4 $kg \cdot m^{-2}$ (SD 2.68) and 74% were nulliparous. Of these 60 women, 57 women completed two sessions. Fifty-six had adequate data from the first session. One woman had unusually high pressures (up to ~200 cmH_2O) during seated activities done in the first session. A pelvic examination done to rule out a pelvic mass or other abnormality was normal. Pressures during her second session were much lower and in the range of other participants; therefore we used data from this second session to describe her intra-abdominal pressures. Using her second session did not change mean values and only decreased the upper range limit of three activities done in the seated position. All, but seven women retained the sensor in the upper vagina during all activities performed in the first session. Four women stated that they felt the sensor fall down into the lower vagina during an activity session, while two stated that it fell out into their underwear.

The mean net rise in intra-abdominal pressure during pelvic muscle contraction in the supine position was 4.4 (SD 4.9) cmH_2O. Despite being given specific instructions to only contract the pelvic floor muscles, seven women were observed to be straining during their attempt to contract the pelvic muscles; when we removed them from the analysis, the mean net rise in intra-abdominal pressure was 3.3 (SD 2.6) cmH_2O. This small increase in pressure was statistically different ($P < 0.001$) from the mean pressure assessed during supine baseline measurement (mean 1.7 SD 1.5 H_2O).

A descriptive summary of intra-abdominal pressures grouped by activity type is provided in Tables I–III. Variability in response was evident in the wide range of pressure values. Sample pressure tracings for activities compared statistically are found in Figures 1 and 2.

There were statistically significant ($P < 0.001$) differences in median maximal intra-abdominal pressure between walking at 4.8 km · h^{-1} on level grade vs walking at 4.8 km · h^{-1} on 7% grade and walking at 4.8 $km \cdot h^{-1}$ on level grade vs walking at 4.3 km · h^{-1} on level grade while carrying 11.4 kg (Table I, Figure 3). However, only the differences in area under the curve and first moment of the area were statistically significant for walking on level

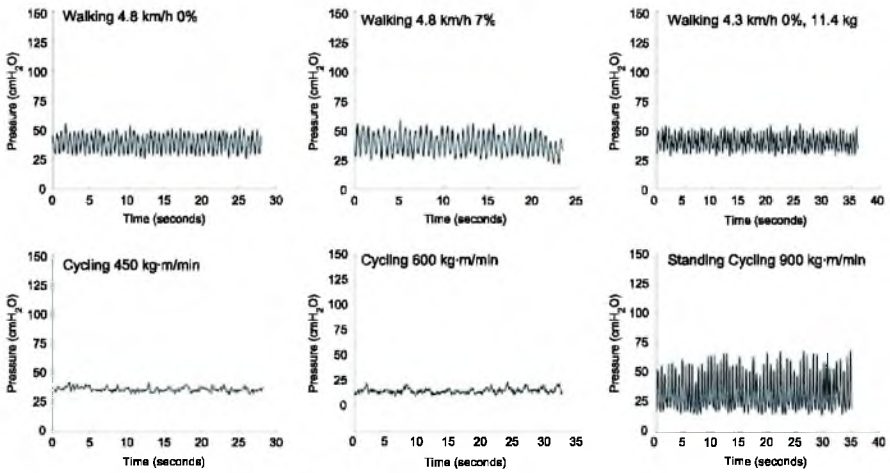

Figure 1. Representative pressure tracings for three levels of walking and for three levels of cycling.

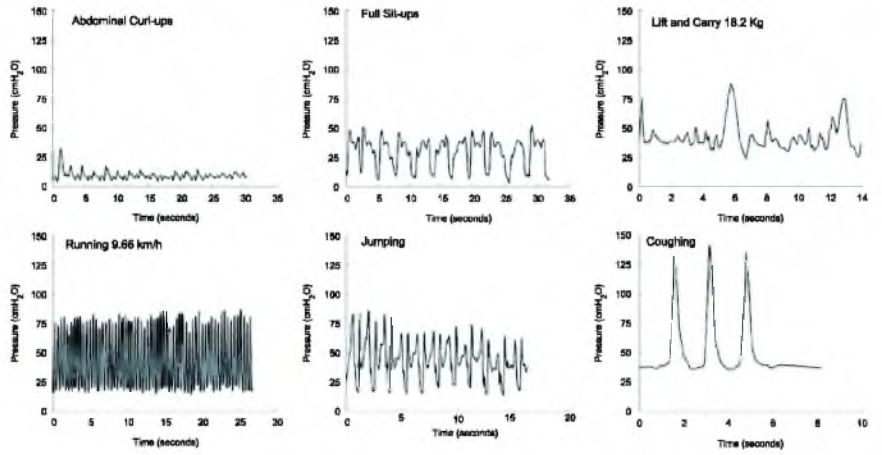

Figure 2. Representative pressure tracings for activities considered to result in high intra-abdominal pressure (IAP).

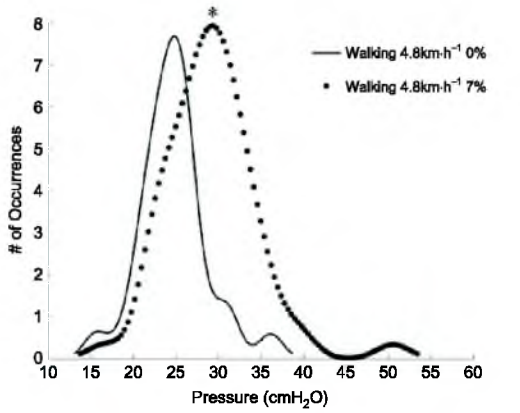

Figure 3. Maximal intra-abdominal pressure (IAP) during walking at 7% grade is higher than maximal IAP during walking on level grade. *$P < 0.0001$.

versus walking at 7% grade. There were no statistically significant differences between walking on level grade with and without carrying 11.4 kg for area under the curve or first moment of the area. For the levels of cycling, intra-abdominal pressure measured by median maximal, area under the curve and first moment of the area during seated cycling at 450 $kg \cdot m \cdot min^{-1}$ was lower than seated cycling at 600 $kg \cdot m \cdot min^{-1}$ which was lower than standing cycling at 900 $kg \cdot m \cdot min^{-1}$ (Table I). Coughing raised the median maximal intra-abdominal pressure more than lifting and carrying 18.2 kg, abdominal curl ups, full sit ups and running; however, coughing was significantly lower than all of these activities except for abdominal curl ups for area under the curve. Coughing remained significantly higher than abdominal curl ups for area under the curve. For first moment of the area, results were similar to area under the curve, as coughing was lower than running and lifting and carrying 18.2 kg; was nearly significantly lower than full sit ups ($P = 0.0057$) but remained higher than abdominal curl ups (Tables I–III).

There was a weak correlation between body mass index and maximal intra-abdominal pressure during jumping ($r = 0.28$, $P = .04$) but no significant correlations between body mass index and maximal intra-abdominal pressure during lifting 18.2 kg ($r = 0.23$, $P = .09$), age and maximal intra-abdominal pressure during lifting 18.2 kg ($r = 0.09$, $P = 0.53$) or age and maximal intra-abdominal pressure during jumping ($r = -0.09$, $P = 0.50$).

Discussion

We describe intra-abdominal pressure for a range of activities using novel, wireless technology. High intra-abdominal pressure during exercise and other physical tasks done at work and in the home have been proposed to increase risk for pelvic floor disorders in women. To study this association, it is important to have valid tools to feasibly collect pressure data during activities that women may do and in typical manner that is not constrained by wired technology. While clinical urogynaecological assessments (coughing and Valsalva manoeuvre) are not usual household or leisure activities, we described these as well to provide a basis of comparison to typical exercise and household tasks.

Our data reflect novel findings of intra-abdominal pressure in women. While most reports focus solely on maximal pressure, we included the calculation of maximal, area under the curve and first moment of the area expressions of intra-abdominal pressure. The area under the curve calculation equally weights time and amplitude of pressure while first moment of the area takes time into consideration but

prioritises the amplitude of pressure. These measures provide new descriptive tools for evaluating intra-abdominal pressure during activity. Because our assessment of maximal pressure reflects a net and not an absolute pressure increase, the weak to non-significant relationship between intra-abdominal pressure during jumping and lifting and carrying 18.2 kg and body mass index is logical. In the relatively young group we tested, it does not appear that age is related to intra-abdominal pressure.

For many activities, the trends for area under the curve and first moment of the area were similar to those of maximal pressure. The differences in levels of cycling reflect this trend quite well. However, some activity comparisons revealed interesting variability. For walking, maximal pressure was significantly higher at 7% grade and for walking with weight when compared to walking at level grade, yet area under the curve and first moment of the area were only different between the uphill walking condition and walking at level grade. The differences between walking on level grade and slightly slower walking while carrying 11.4 kg were not significant for area under the curve and first moment of the area. The time component for these activities was standardised and the amplitude differences reflected the entire area under a constructed line of maximal pressure. Therefore, the increase in grade was a greater influence on area under the curve and first moment of the area expressions of intra-abdominal pressure during walking than the addition of carrying weight similar to that of a toddler.

The activities performed in this study produce intra-abdominal pressures that vary considerably in rise time, peak pressure and duration. We have previously shown that the intra-vaginal pressure transducer is capable of measuring rapidly changing pressures without the overshoot or resonance that is typical of fluid filled systems (Coleman et al., 2010; Johnson, Rosenbluth, Nygaard, Parikh, & Hitchcock, 2009). These previous studies evaluated the pressure transducer response to both an impulse and swept sine wave and showed that the natural frequencies and damping coefficients were incalculable demonstrating no measurable overshoot during the swept sine or impulse tests.

The comparison of coughing to activities that are classically restricted in post-surgical patients revealed different trends in maximal, area under the curve and first moment of the area intra-abdominal pressure. While coughing is recognised as producing high maximal pressure, as we have demonstrated, the relatively short duration of coughing in our protocol (three maximal coughs in standing position) resulted in lower measures of area under the curve and first moment of the area than most comparisons. Because of amplitude differences, however, coughing remained significantly higher than abdominal curl ups for area under the curve and first moment of the area, despite curl ups having longer duration. We specifically examined area under the curve intra-abdominal pressure of coughing and lifting and carrying 18.2 kg since participants were directed to do each of these activities three times (Figure 4). The median maximal pressure was highest for coughing, but the area under the curve pressure was highest for the lifting task, because completing the lifting task involved sustained elevation of pressure over greater duration to complete the three repetitions.

Some of the intra-abdominal pressures during activities we tested have been described previously; our results fit in the range of others (Cobb et al., 2005; Essendrop, Hye-Knudsen, Skotte, Hansen, & Schibye, 2004; Gerten et al., 2008; Guttormson et al., 2008; Hagins, Pietrek, Sheikhzadeh, Nordin, & Axen, 2004; Weir et al., 2006), though it is important to note that the variability in intra-abdominal pressure between different studies is large and due in part to the variety of methods used for collecting

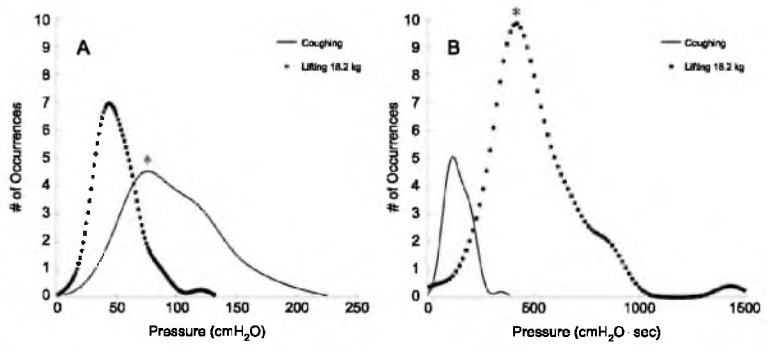

Figure 4. (A) Maximal intra-abdominal pressure (IAP) during 3 maximal coughs is greater than maximal IAP while lifting and carrying 18.2 kg. $^*P < 0.0001$. (B) Area under the curve (AUC) IAP while lifting and carrying 18.2 kg is greater than AUC IAP during 3 maximal coughs. $^*P < 0.0001$.

intra-abdominal pressure as well as to multiple methods for calculating maximal pressure. Of greater clinical interest is the wide range of intra-abdominal pressures we found amongst different women doing the same activity. We found the greatest degree of variability in activities that were novel and/or required participants to control their effort. For example, walking on the treadmill exhibited little variability. Walking is a familiar activity and the speed and grade, which we presumed would be tolerable for all participants, afforded little opportunity for participants to regulate effort. On the other hand, Valsalva manoeuvre, jumping and standing cycling showed great variability. All required participants to exert effort based upon the instruction given and may have been novel to participants. Valsalva manoeuvre and jumping were to be performed at maximal effort. The cadence and resistance for standing cycling were set the same for all participants, but it was evident that many women did not normally do this activity.

Variability in intra-abdominal pressure for a given activity is of interest to clinicians especially for activities that may be restricted in the post-surgical patient or in those at risk for pelvic floor disorders. There is no established, data-based threshold of maximal intra-abdominal pressure that is used to guide activity restriction for safety purposes. Ideally, a population of women would be followed prospectively to determine their intra-abdominal pressure exposure and then determine risk for diagnosis of a pelvic floor disorder on the basis of that exposure, which is not practical. From laboratory studies such as this, a theoretical threshold could be established (for example, activities with median net intra-abdominal pressure > 60 cmH_2O or some other cut-point) and activities that elevate intra-abdominal pressure above that threshold would be restricted. However, given the variability of intra-abdominal pressure, some women would be unnecessarily restricted from doing healthful activity. There is great need to better understand the causes of variability in intra-abdominal pressure with activity, so that personal activity restrictions can be made when appropriate, such as in the post-surgical patient. At present, we believe the large individual variation in intra-abdominal pressure prohibits generalised activity restriction recommendations.

This study has several strengths. We used a novel, wireless intra-vaginal pressure transducer with known validity. It was well tolerated, as evidenced by our low attrition rate. We describe a variety of activity-related intra-abdominal pressures with a relatively large sample size. All of the activities were standardised by using the same equipment and scripted descriptions with all participants. The activities we describe include clinically relevant assessments as well as common exercise and household activities, some of which are typically restricted by clinicians. The addition of area under the curve and first moment of the area expressions of intra-abdominal pressure may provide more tools to assess potential relationships between strenuous physical activity and pelvic floor disorders.

Our study is not without limitations. We measured pressures in the upper vagina, which have been shown to approximate intra-abdominal pressure measured via rectal or bladder transducers (Al-Taher, Sutherst, Richmond, & Brown, 1987; James, Niblett, MacNaughton, & Shaldon, 1987). However, measuring intra-abdominal pressure from any cavity other than the actual intra-abdominal cavity adds some element of uncertainty. Measuring from the vagina likely adds unknown pressures from viscera, vaginal smooth muscle and other unknown sources. Because we are interested in how and whether intra-abdominal pressure of varying magnitude impacts the pelvic floor, we believe it is important to assess pressures in the upper vagina or upper rectum, as these pressures would be most likely to transmit to the pelvic floor (i.e., the forces exerted on the pelvic floor include not only intra-abdominal pressure but also upper vaginal and rectal forces). Based on the low net pressure rise observed while participants performed pelvic muscle contraction (3–5 cm H_2O, rather than the 25–50 cm H_2O rise in pressure seen during an actual pelvic muscle contraction), we think it is reasonable to assume that the sensor was generally measuring upper vaginal pressure and not pelvic muscle contraction strength, though it is possible that in some women it may have been. Additionally, our sample consisted of young, healthy and active women to decrease the risk of adverse events during exercise participation. The pressures we describe herein are not generalisable to older and less active women with chronic conditions. While we directly measured height and weight for body mass index ($kg \cdot m^{-2}$) calculation, which has previously been shown to influence intra-abdominal pressure, assessment of body density and composition and other measures of physical fitness was beyond our scope, and in future research may explain some of the variability in pressure response to activity. Lastly, the time segments and specific repetitions for each of the activities in our protocol were relatively short for logistical purposes, which limit our ability to fully explore the meaningfulness of area under the curve and first moment of the area measures of intra-abdominal pressure.

Summary

The assessment of activity-induced intra-abdominal pressure and its potential link to pelvic floor disorders

is not a topic routinely addressed in the exercise science literature. In order to explore this potential link, valid methods must be established to assess baseline and change in intra-abdominal pressure over time to determine whether certain activities increase risk for pelvic floor disorders. The descriptive information we provide may be especially relevant to educators and to those who provide exercise training for women in the context of fitness, clinical or research settings. Further research is needed to understand variability in intra-abdominal pressure amongst women before instituting exercise guidelines and activity restriction based on intra-abdominal pressure.

Conflict of interest

No author of this manuscript has any conflicts of interest.

Acknowledgment

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APPENDIX E

ENGINEERING DRAWINGS

Part Number	Revision	Drawing Number	Description
000-001	00	ADA-0001	Battery Protector
006-001	00	ADA-0002	Battery Contact Long
005-001	00	ADA-0003	Battery Contact Short
004-001	00	ADA-0004	Short Protector
003-001	00	ADA-0005	Contact Protector
002-001	00	ADA-0006	IEC-LR43 Battery
001-001	00	ADA-0007	Rounded Spacer
007-001	00	ADA-0008	Shrink Tubing Polyester Clear
N/A	00	ADA-0009	Capsule Drawings 1st-4th
N/A	00	ADA-0010	Battery Package Assembly
011-001	00	ADA-0011	Gen4 Capsule Neg Female
010-001	00	ADA-0012	Gen4 Capsule Neg Male
012-001	00	ADA-0013	Generation 4 Capsule
N/A	00	ADA-0014	Electronics Package Top
013-001	00	ADA-0015	Sensor Die 3SC 2000 IT
014-001	00	ADA-0016	MSP430F2132TRHBT
015-001	00	ADA-0017	ZMD 31014
016-001	00	ADA-0018	Vent Tube IVT Pebax 63335A
017-001	00	ADA-0019	Strain Relief Tether
N/A	00	ADA-0021	Electronics Package Bottom
019-001	00	ADA-0022	Zarlink ZL70101
N/A	00	ADA-0023	Board Sketch
002-001	01	ADA-0024	Energizer CR1632 Battery
004-001	01	ADA-0025	Short Protector
003-001	01	ADA-0026	Contact Protector
N/A	00	ADA-0027	Injection Mold Assembly
008-001	00	ADA-0028	IMD Circuit Board
009-001	00	ADA-0029	RF Circuit Board
008-001	01	ADA-0030	IMD Circuit Board
009-001	01	ADA-0031	RF Circuit Board
006-001	01	ADA-0032	Battery Contact Long
005-001	01	ADA-0033	Battery Contact Short
020-001	00	ADA-0034	O-Ring
000-001	01	ADA-0035	Battery Protector
007-001	01	ADA-0036	Shrink Tubing Polyester Clear
N/A	01	ADA-0037	Battery Package Assembly
N/A	01	ADA-0038	Electronics Package Top
N/A	01	ADA-0039	Electronics Package Bottom
021-001	00	ADA-0040	Circuit Board Holder
N/A	00	ADA-0041	Circuit Boards
N/A	00	ADA-0042	Complete Assembly
N/A	00	ADA-0043	Master Assembly
022-001	00	ADA-0044	Capsule Cap
023-001	00	ADA-0045	Capsule Cap Outlet Half
024-001	00	ADA-0046	Capsule Cap Injection Half
N/A	00	ADA-0047	Electronics Package
025-001	00	ADA-0048	Cover for Base Station LED
026-001	04	ADA-0049	Ribbon Wire

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
00	INITIAL RELEASE		9/24/10	TC / /
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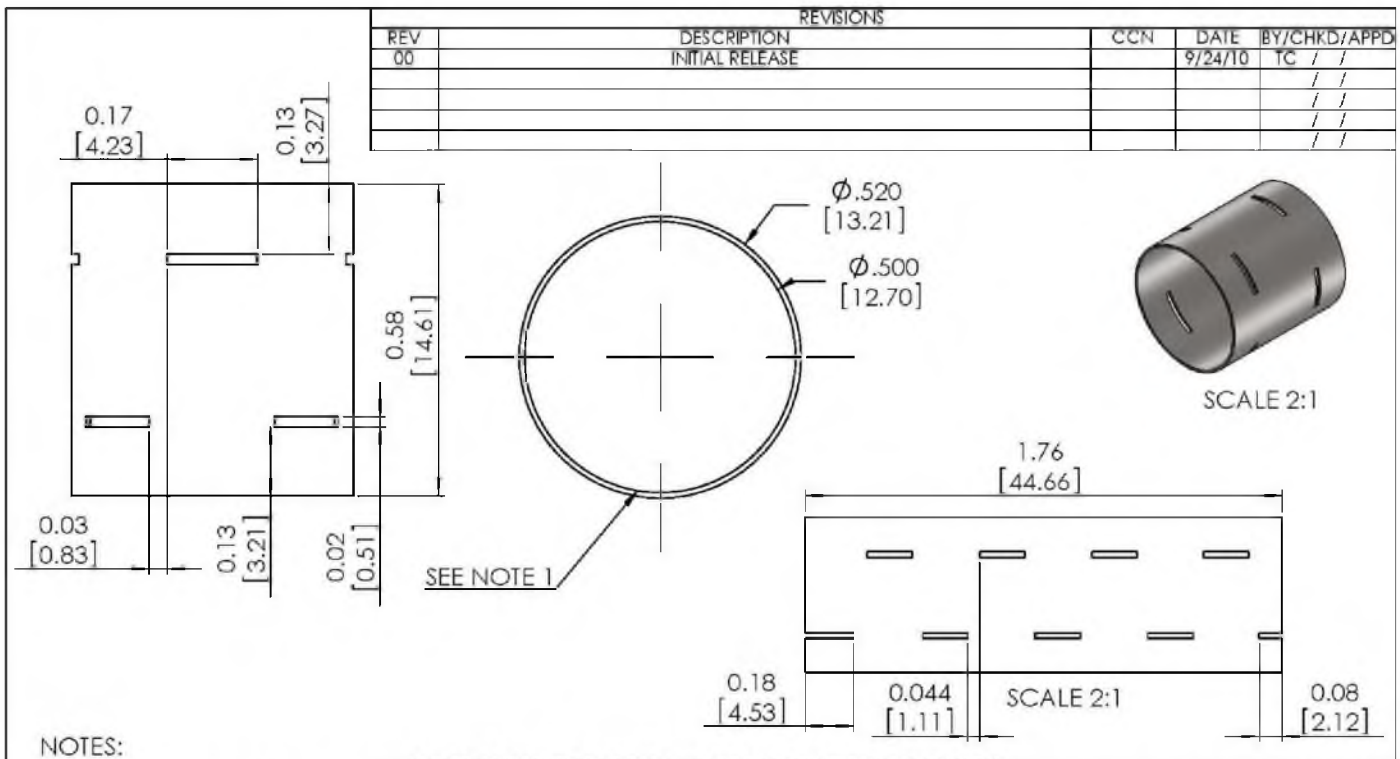


NOTES:

1) THIS PART IS MODELED FROM FLAT PART

IPS

THIRD ANGLE PROJECTION

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

MATERIAL: POLYESTER

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	9/24/10
CHECKED	
APPROVED	

SCALE: 4:1

DO NOT SCALE DRAWING

Department of Bioengineering

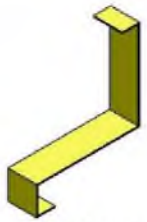
THE UNIVERSITY OF UTAH

TITLE: WRAPS - BATTERY PROTECTOR

DWG. NO. ADA-0001

SIZE	PART/MAT'L NO.	DOC REV.
A	000-001	00

DOC NO. 1 | SHEET 1 OF 1



SCALE 2:1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
00	INITIAL RELEASE		9/24/10	TC / /
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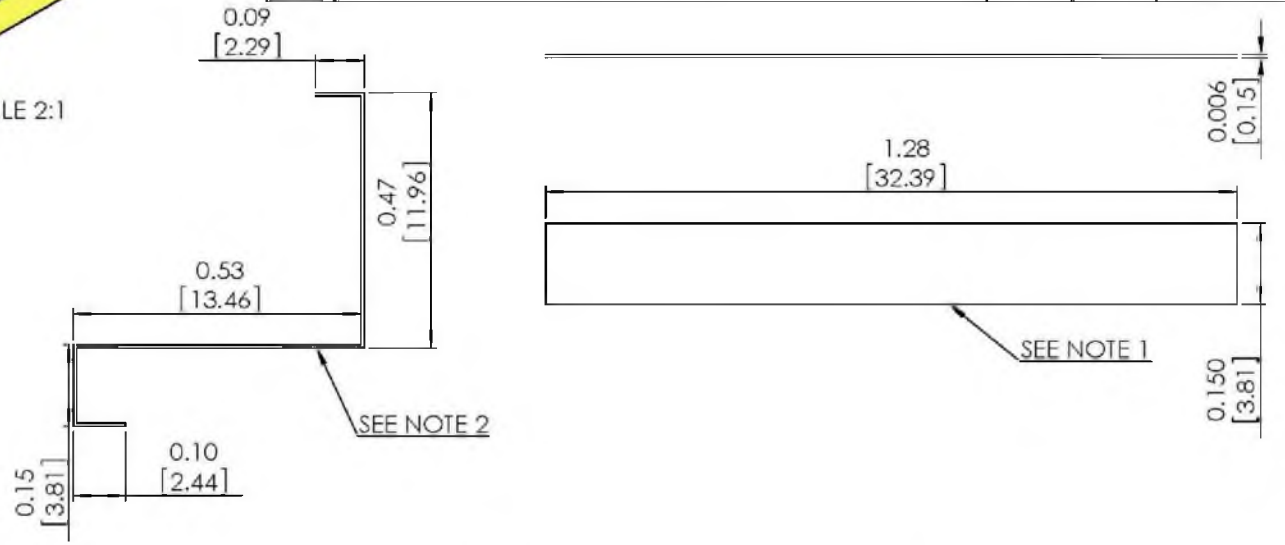
				/ /
				/ /



NOTES:

1) PART IS CUT FLAT

2) PART IS BENT TO FIT ONCE ASSEMBLED

IPS

THIRD ANGLE PROJECTION

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

MATERIAL:

BRASS SHIM STOCK

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	9/24/10
CHECKED	
APPROVED	

SCALE: 4:1

DO NOT SCALE DRAWING

Department of Bioengineering

THE UNIVERSITY OF UTAH

TITLE: WRAPS -BATTERY CONTACT LONG

DWG. NO. ADA-0002

SIZE	PART/MAT'L NO.	DOC REV.
A	006-001	00

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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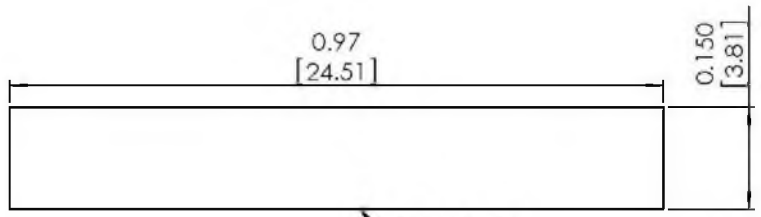

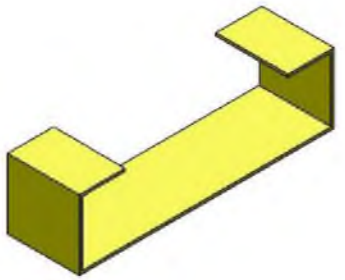

NOTES:

1) PART IS CUT FLAT

2) PART IS BENT TO FIT ONCE ASSEMBLED

IPS

THIRD ANGLE PROJECTION

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

MATERIAL:

BRASS SHIM STOCK

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	9/24/10
CHECKED	
APPROVED	

SCALE: 5:1

DO NOT SCALE DRAWING

Department of Bioengineering

THE UNIVERSITY OF UTAH

TITLE: WRAPS - BATTERY CONTACT SHORT

DWG. NO. A DA-0003

SIZE	PART/MAT'L NO.	DOC REV.
A	005-001	00

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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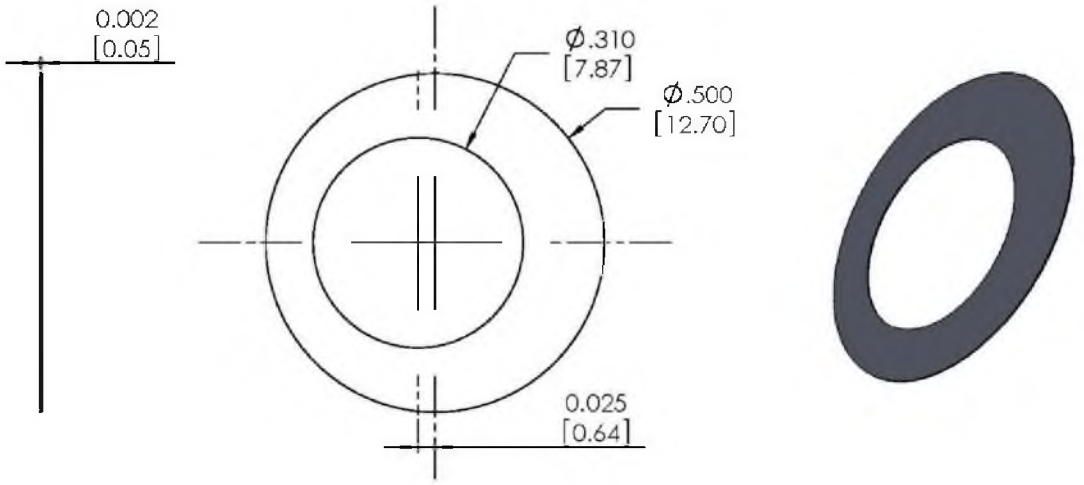
				/ /



UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	9/24/10
CHECKED	
APPROVED	

Department of Bioengineering
THE UNIVERSITY OF UTAH

IPS

THIRD ANGLE PROJECTION

MATERIAL:
POLYESTER

SPEC NO. N/A

SCALE: 5:1

DO NOT SCALE DRAWING

TITLE: WRAPS - SHORT PROTECTOR

DWG. NO. A DA-0004

SIZE	PART/MAT'L NO.	DOC REV.
A	004-001	00

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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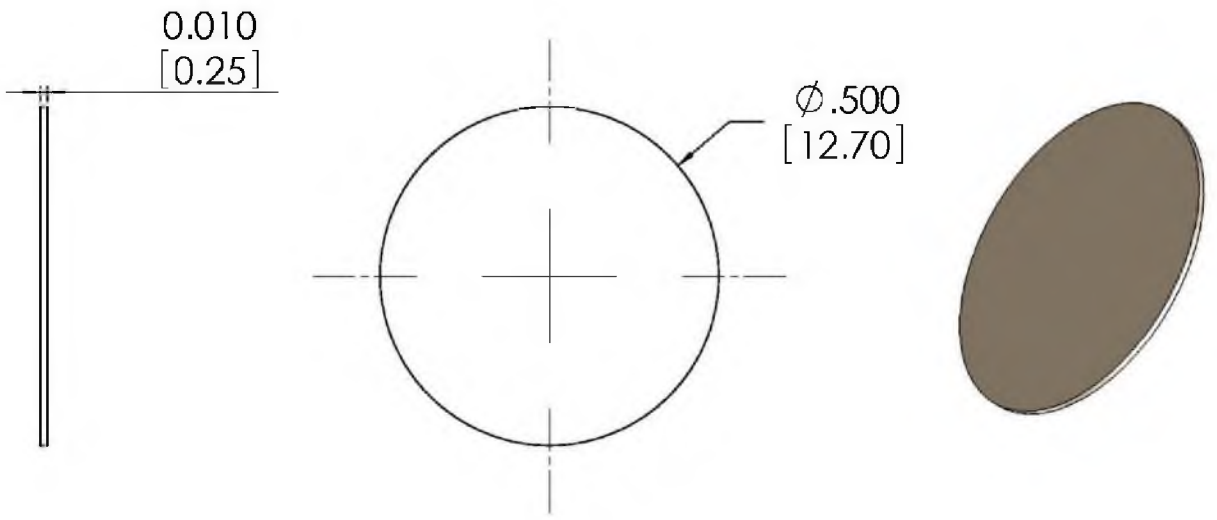

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES	SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE	Department of Bioengineering
MACHINED SURFACES DECIMAL .X ±.25 .XX ±.01 .XXX ±.003 ANG ±1°	APPROVALS / DRAWN T. COLEMAN / APPROVED — DATE 9/24/10	THE UNIVERSITY OF UTAH
IPS THIRD ANGLE PROJECTION	MATERIAL: POLYESTER	TITLE: WRAPS -Contact Protector
	THIS DOCUMENT IS THE CONFIDENTIAL AND PROPRIETARY PROPERTY OF THE UNIVERSITY OF UTAH. REPRODUCTION, RELEASE, OR REVISION WITHOUT EXPRESS PERMISSION IS STRICTLY PROHIBITED AND MAY RESULT IN CIVIL AND CRIMINAL PENALTIES.	DWG. NO. A DA-0005
	SPEC NO. N/A	SCALE: 5:1
	DO NOT SCALE DRAWING	SIZE A / PART/MAT'L NO. 003-001 / DOC REV. 00
		DOC NO. 1 / SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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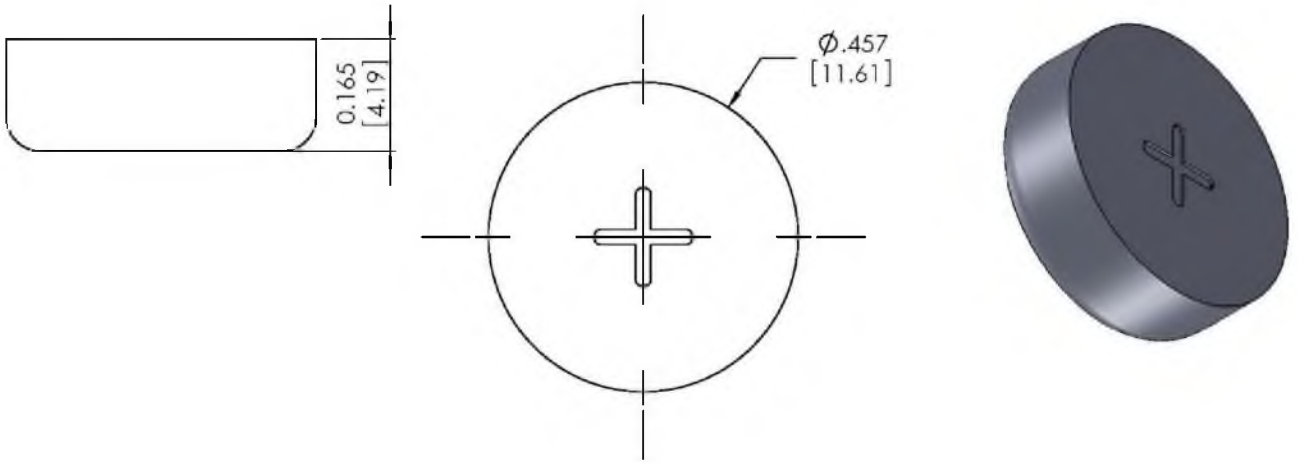
				/ /
				/ /



UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

DECIMAL .X ±.25, .XX ±.01, .XXX ±.003

ANG ±1°

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	9/2710
CHECKED	
APPROVED	

Department of Bioengineering
THE UNIVERSITY OF UTAH

IPS

THIRD ANGLE PROJECTION

MATERIAL:
MANGANESE DIOXIDE BATTERY

SPEC NO. N/A

SCALE: 5:1

DO NOT SCALE DRAWING

TITLE: WRAPS - IEC-LR43 BATTERY

DWG. NO. ADA-0006

SIZE	PART/MAT'L NO.	DOC REV.
A	002-001	00

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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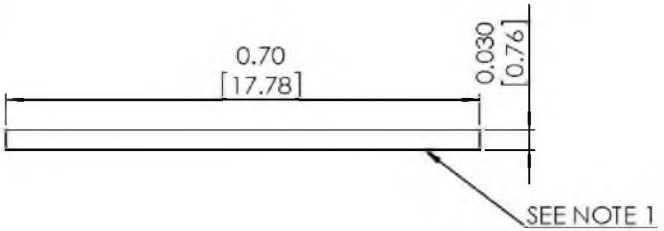
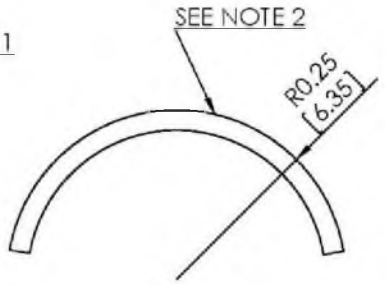
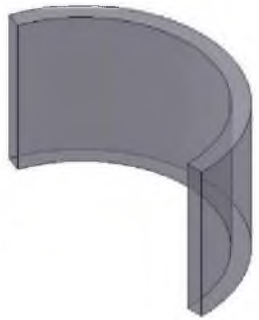
				/ /







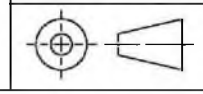
NOTES:

1) PART IS CUT FLAT

2) PART IS BENT TO FIT ONCE ASSEMBLED

IPS

THIRD ANGLE PROJECTION



UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

MATERIAL:
LOW DENSITY POLYETHYLENE

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	9/24/10
CHECKED	
APPROVED	

SCALE: 5:1

DO NOT SCALE DRAWING

Department of Bioengineering
THE UNIVERSITY OF UTAH

TITLE: WRAPS - ROUNDED SPACER

DWG. NO. ADA-0007

SIZE	PART/MAT'L NO.	DOC REV.
A	001-001	00

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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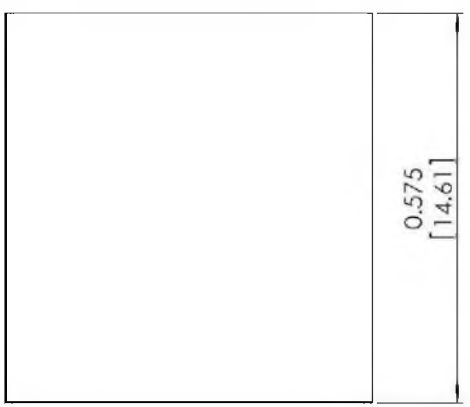
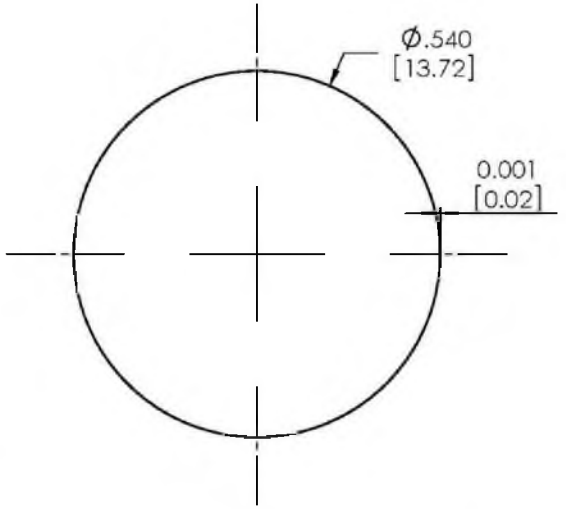




SCALE 2:1

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

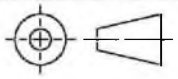
MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

IPS

THIRD ANGLE PROJECTION



MATERIAL:
CLEAR POLYESTER

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	10/27/10
CHECKED	
APPROVED	

SCALE: 5:1

DO NOT SCALE DRAWING

Department of Bioengineering
THE UNIVERSITY OF UTAH

TITLE: WRAPS - SHRINK TUBING

DWG. NO. ADA-0008

SIZE	PART/MAT'L NO.	DOC REV.
A	007-001	00

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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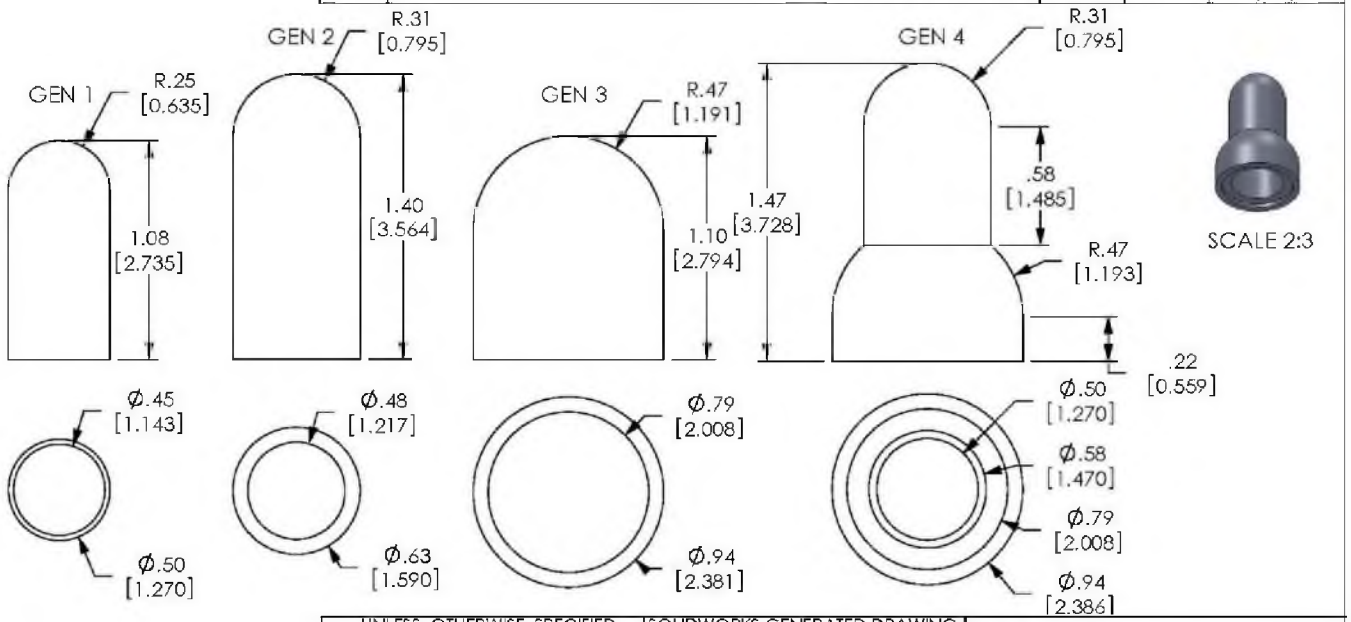

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

IPS

THIRD ANGLE PROJECTION

MATERIAL:
NUSIL MED 6010
SILICONE ELASTOMER

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T.COLEMAN	9/24/10
CHECKED N/A	N/A
APPROVED N/A	N/A

SCALE: 2:1

DO NOT SCALE DRAWING

Department of Bioengineering

THE UNIVERSITY OF UTAH

TITLE: WRAPS - CAPSULE DRAWINGS

DWG. NO. ADA-0009

SIZE	PART/MAT'L NO.	DOC REV.
A	N/A	00

DOC NO. 1 SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
00	INITIAL RELEASE		9/23/10	TC / /
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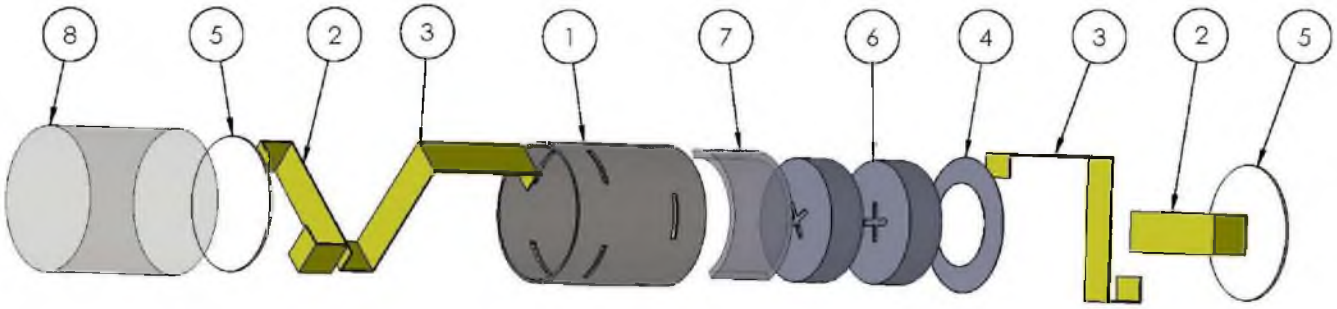


ITEM NO.	PART NO.	DWG. (REF. ONLY)	DESCRIPTION	QTY.
1	000-001	ADA-0001	Battery Protector	1
2	005-001	ADA-0003	Battery Contact Short	2
3	006-001	ADA-0002	Battery Contact Long	2
4	004-001	ADA-0004	Short Protector	1
5	003-001	ADA-0005	Contact Protector	2
6	002-001	ADA-0006	IEC-LR43 Battery	2
7	001-001	ADA-0007	Rounded Spacer	1
8	007-001	ADA-0008	Shrink Tubing	1

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25 .XX ±.13

ANG ±1°

MATERIAL:

SPEC NO. N/A

IPS

THIRD ANGLE PROJECTION

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	9/23/10
CHECKED	
APPROVED	

SCALE: 2:1

DO NOT SCALE DRAWING

Department of Bioengineering

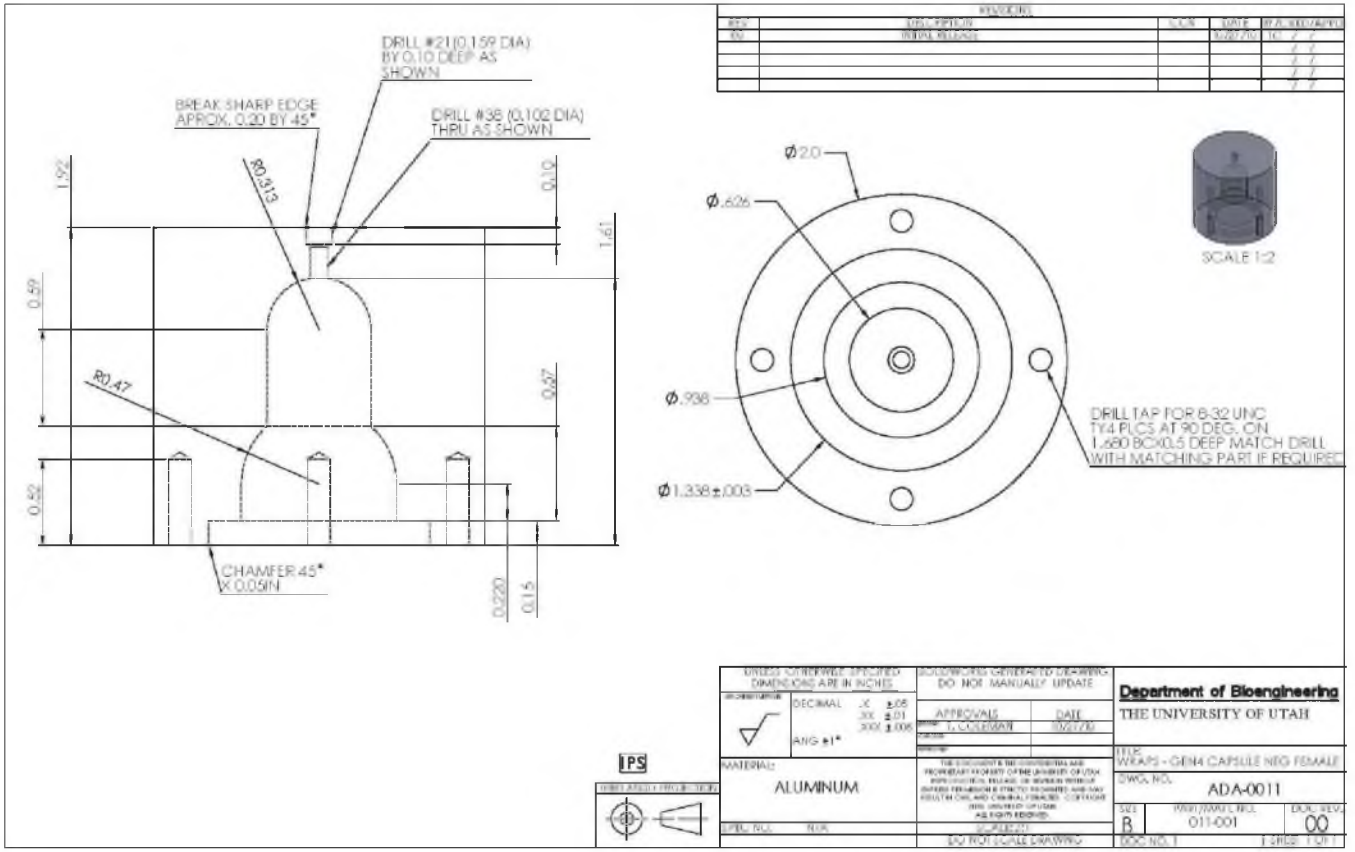
THE UNIVERSITY OF UTAH

TITLE: WRAPS - BATTERY PACKAGE

DWG. NO. ADA-0010

SIZE	PART/MAT'L NO.	DOC REV.
A	SEE SPEC.	00

DOC NO. 1 | SHEET 1 OF 1


DRILL #21 (0.159 DIA) BY 0.10 DEEP AS SHOWN
BREAK SHARP EDGE APPROX. 0.20 BY 45°
DRILL #38 (0.102 DIA) THRU AS SHOWN
R0.313
1.92
0.10
1.61
0.59
0.67
R0.47
0.52
CHAMFER 45° X 0.05IN
0.220
0.15
Ø2.0
Ø.626
Ø.938
Ø1.338±.003
DRILL TAP FOR 8-32 UNC THRU 4 PLCS AT 90 DEG. ON 1.680 BCX0.5 DEEP MATCH DRILL WITH MATCHING PART IF REQUIRED
SCALE 1:2
REVISIONS
REV
DESCRIPTION
ECN
DATE
BY
APPROVED
00
INITIAL RELEASE
9/27/10
TC
UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES
DECIMAL .X ±.05 .XX ±.01 .XXX ±.005
ANG ±1°
SOLIDWORKS GENERATED DRAWING DO NOT MANUALLY UPDATE
APPROVALS
DATE
T. COLEMAN
9/27/10
MATERIAL:
ALUMINUM
FINISH:
NONE
DO NOT SCALE DRAWING
Department of Bioengineering
THE UNIVERSITY OF UTAH
TITLE:
WRAPS - GEN4 CAPSULE NEO FEMALE
DWG. NO.
ADA-0011
SIZE
B
PART/ASSY NO.
011-001
DOC. REV.
00
DOC NO. 1
SHEET 1 OF 1

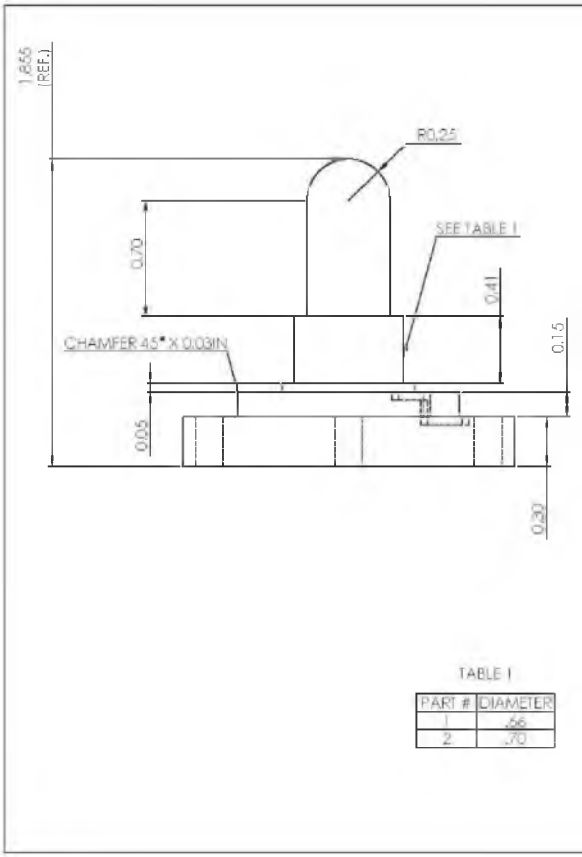


TABLE 1

PART #	DIAMETER
1	.56
2	.70

REVISIONS				
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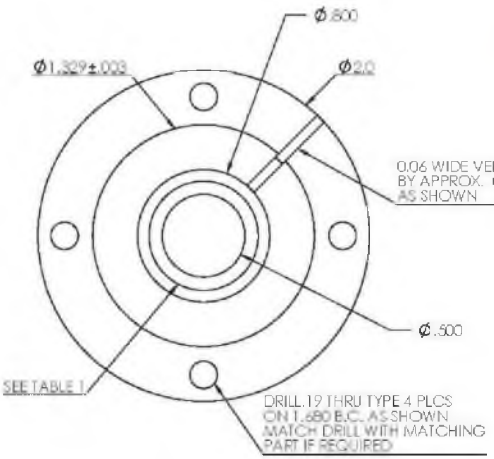
			/ /	



SCALE 1:2

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

DECIMAL .X ±.05 .XX ±.01 .XXX ±.005

ANG ±1°

SOLIDWORKS GENERATED DRAWING. DO NOT MANUALLY UPDATE

APPROVALS	DATE
L. COLEMAN	10/28/10

Department of Bioengineering

THE UNIVERSITY OF UTAH

IPS

THIRD ANGLE PROJECTION

MATERIAL: ALUMINUM

FINISH: N/A

SCALE: 2:1

DO NOT SCALE DRAWING

TITLE: WRAPS - GEN4 CAPSULE NEG MALE

DWG. NO. ADA-0012

SIZE	PART/MAT'L NO.	DOC REV.
B	010-001	00

DO NOT SCALE DRAWING | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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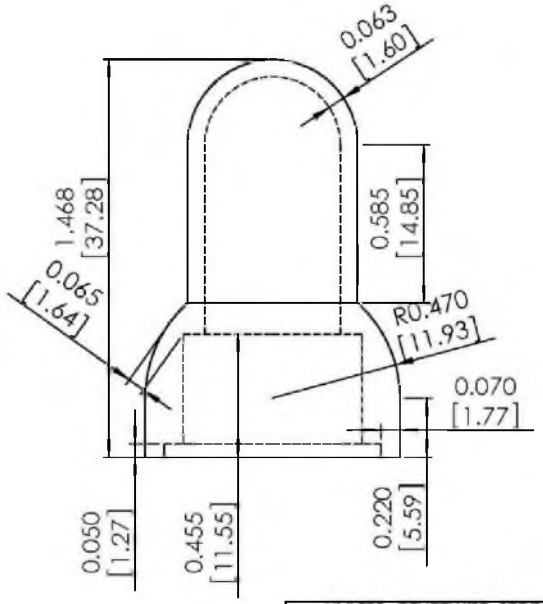

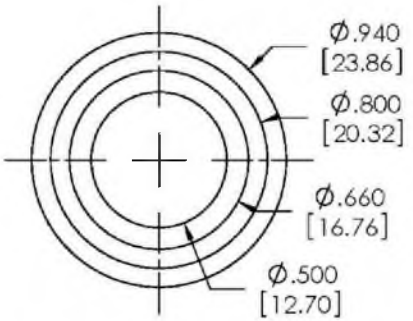

SCALE 1:1

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

DECIMAL .X ±.25 .XX ±.01 .XXX ±.003

ANG ±1°

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	10/04/10
CHECKED	
APPROVED	

Department of Bioengineering
THE UNIVERSITY OF UTAH

IPS

THIRD ANGLE PROJECTION

MATERIAL:
SILICONE ELASTOMER
NUSIL MED6010

SPEC NO. N/A

SCALE: 2:1

DO NOT SCALE DRAWING

TITLE: WRAPS - GENERATION4 CAPSULE

DWG. NO. ADA-0013

SIZE	PART/MAT'L NO.	DOC REV.
A	012-001	00

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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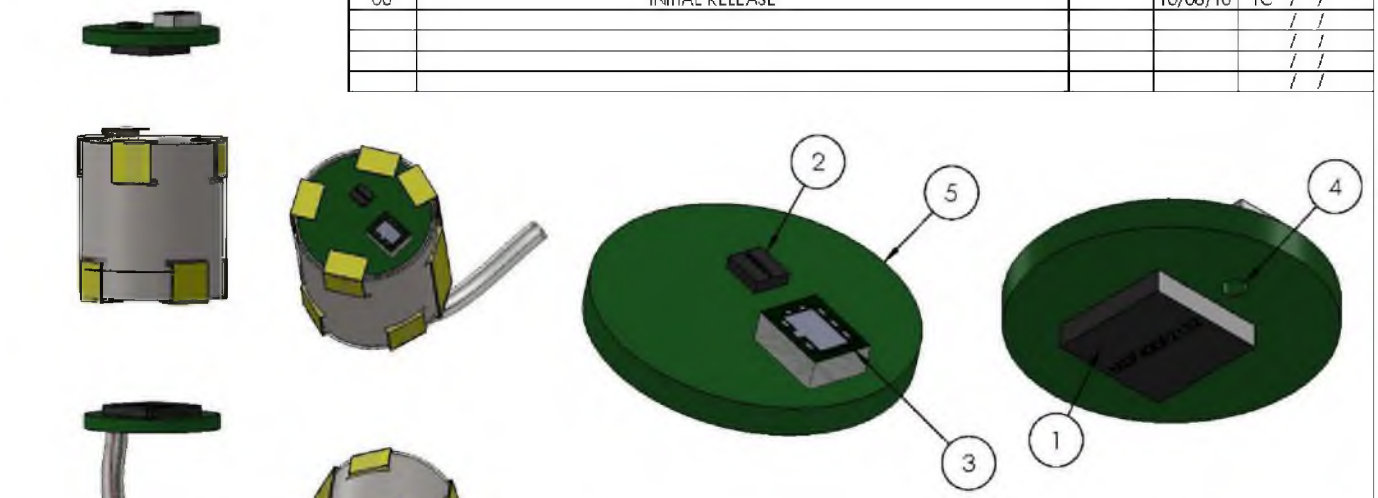

ITEM NO.	PART NO.	DWG. (REF. ONLY)	DESCRIPTION	QTY.
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2	015-001	ADA-0017	ZMD31014	1
3	013-001	ADA-0015	Sensor Dye	1
4	N/A	N/A	Atmospheric Vent	1
5	008-001	ADA-0028	Circuit Board 1	1

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

IPS

THIRD ANGLE PROJECTION

MATERIAL: N/A

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	10/08/10
CHECKED	
APPROVED	

SCALE: 2:1

DO NOT SCALE DRAWING

Department of Bioengineering

THE UNIVERSITY OF UTAH

TITLE: WRAPS - ELECTRONICS PACKAGE TOP

DWG. NO. ADA-0014

SIZE	PART/MAT'L NO.	DOC REV.
A	N/A	00

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
00	INITIAL RELEASE		10/27/10	TC / /
				/ /
				/ /
				/ /
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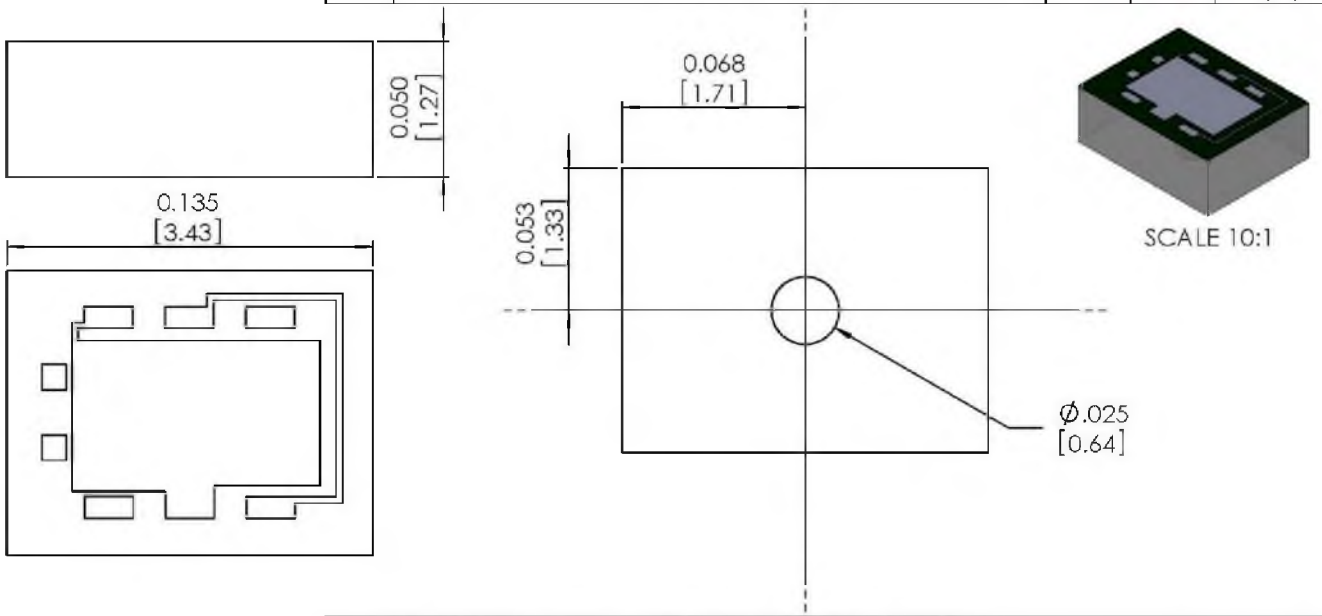

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

IPS

THIRD ANGLE PROJECTION

MATERIAL:
SILICON CRYSTAL

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	10/27/10
CHECKED	
APPROVED	

SCALE: 20:1

DO NOT SCALE DRAWING

Department of Bioengineering
THE UNIVERSITY OF UTAH

TITLE: WRAPS - SENSOR DIE

DWG. NO. ADA-0015

SIZE	PART/MAT'L NO.	DOC REV.
A	013-001	00

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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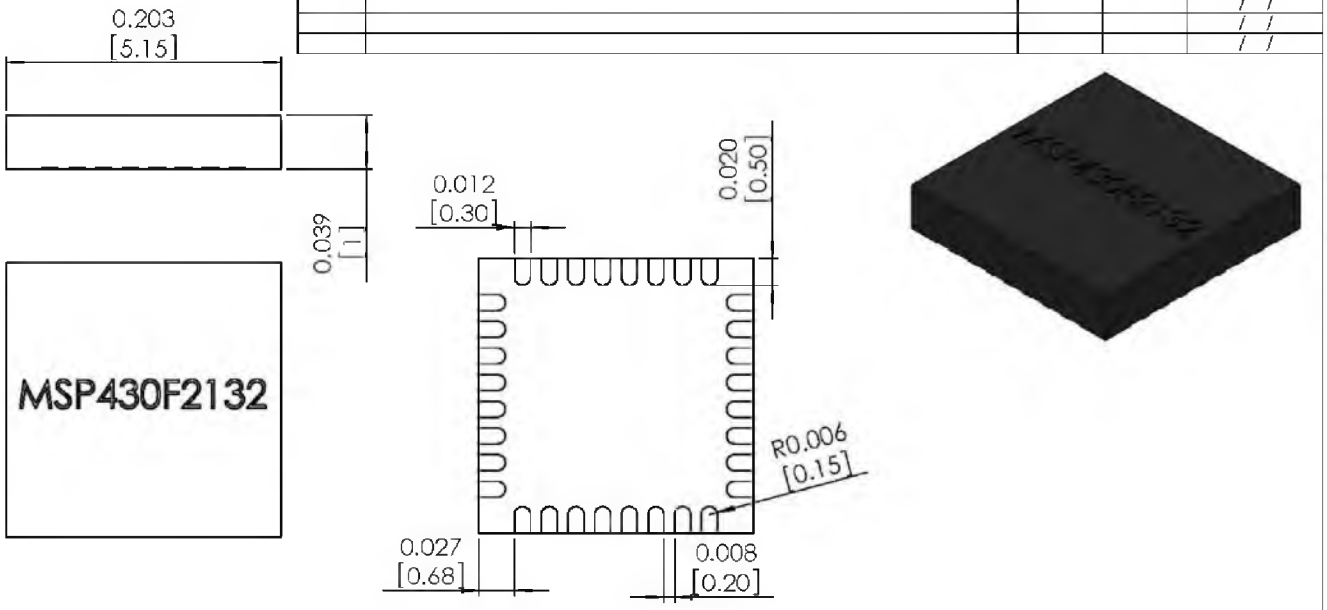

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

MATERIAL:

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	10/27/10
CHECKED	
APPROVED	

SCALE: 10:1

DO NOT SCALE DRAWING

IPS

THIRD ANGLE PROJECTION

Department of Bioengineering

THE UNIVERSITY OF UTAH

TITLE: WRAPS - MSP430 MICROCONTROLLER

DWG. NO. ADA-0016

SIZE	PART/MAT'L NO.	DOC REV.
A	014-001	00

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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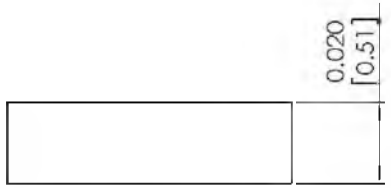

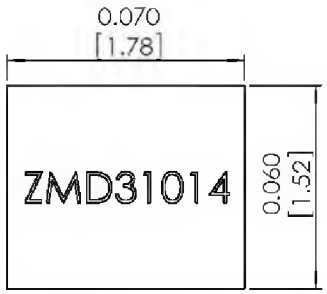

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES MACHINED SURFACES DECIMAL .X ±.25 .XX ±.01 .XXX ±.003 ANG ±1°	SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE APPROVALS / DATE DRAWN T. COLEMAN 10/27/10 CHECKED APPROVED	**Department of Bioengineering** THE UNIVERSITY OF UTAH
IPS THIRD ANGLE PROJECTION	MATERIAL:	TITLE: WRAPS - ZMD SIGNAL CONDITIONER
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SPEC NO. N/A	SCALE: 30:1	SIZE A / PART/MAT'L NO. 015-001 / DOC REV. 00
	DO NOT SCALE DRAWING	DOC NO. 1 / SHEET 1 OF 1

REVISIONS				
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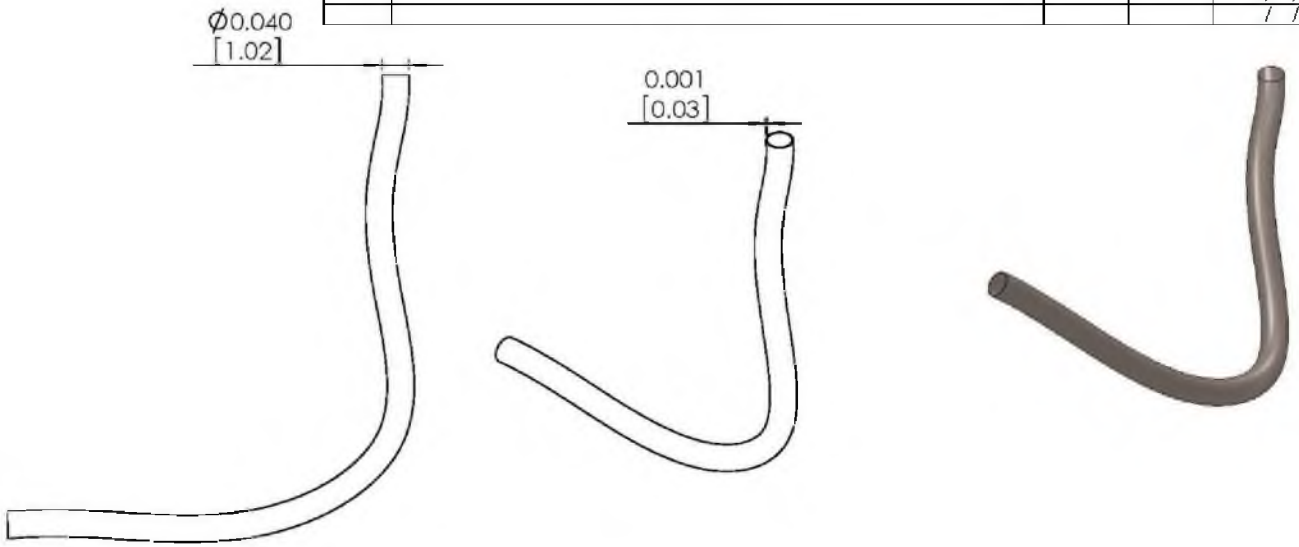

NOTE:

VENT TUBE LEGNTH TBD

IPS

THIRD ANGLE PROJECTION

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

MATERIAL:

PEBAX 63335A

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	10/27/10
CHECKED	
APPROVED	

SCALE: 5:1

DO NOT SCALE DRAWING

Department of Bioengineering

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TITLE: WRAPS - VENT TUBE

DWG. NO. ADA-0018

SIZE	PART/MAT'L NO.	DOC REV.
A	016-001	00

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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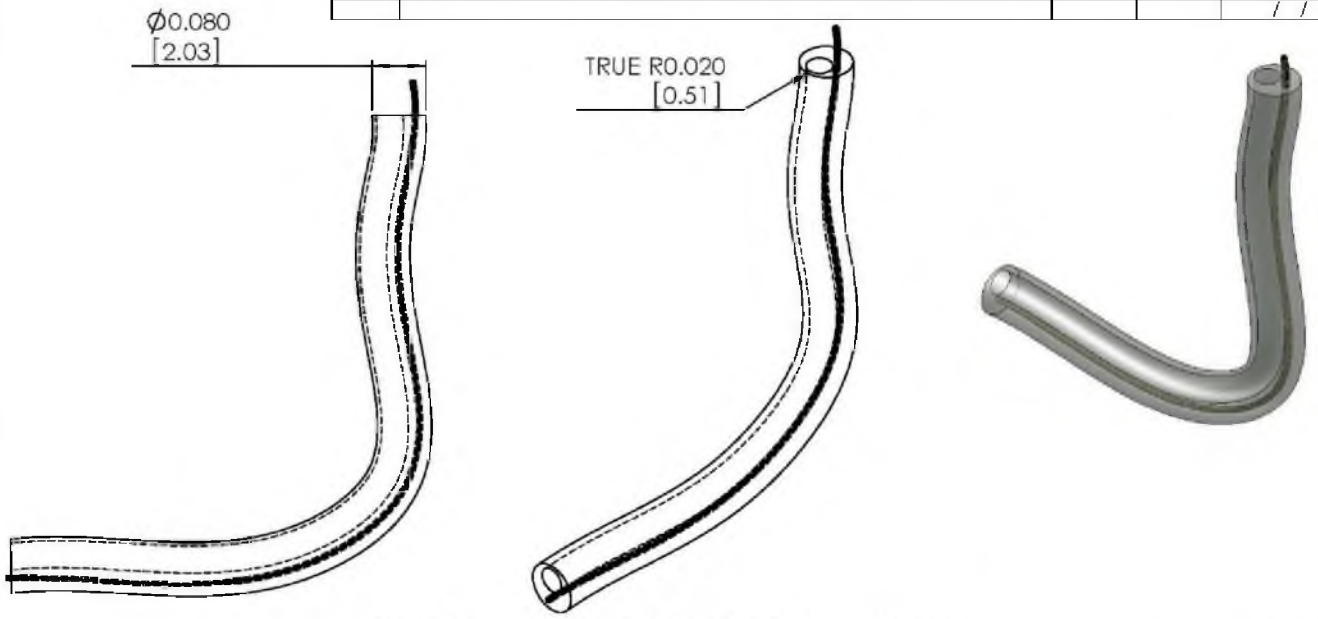

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

IPS

THIRD ANGLE PROJECTION

MATERIAL:
SILICONE ELASTOMER

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	10/27/10
CHECKED	
APPROVED	

SCALE: 5:1

DO NOT SCALE DRAWING

Department of Bioengineering
THE UNIVERSITY OF UTAH

TITLE: WRAPS - STRAIN RELEIF TEHTER

DWG. NO. ADA-0019

SIZE	PART/MAT'L NO.	DOC REV.
A	017-001	00

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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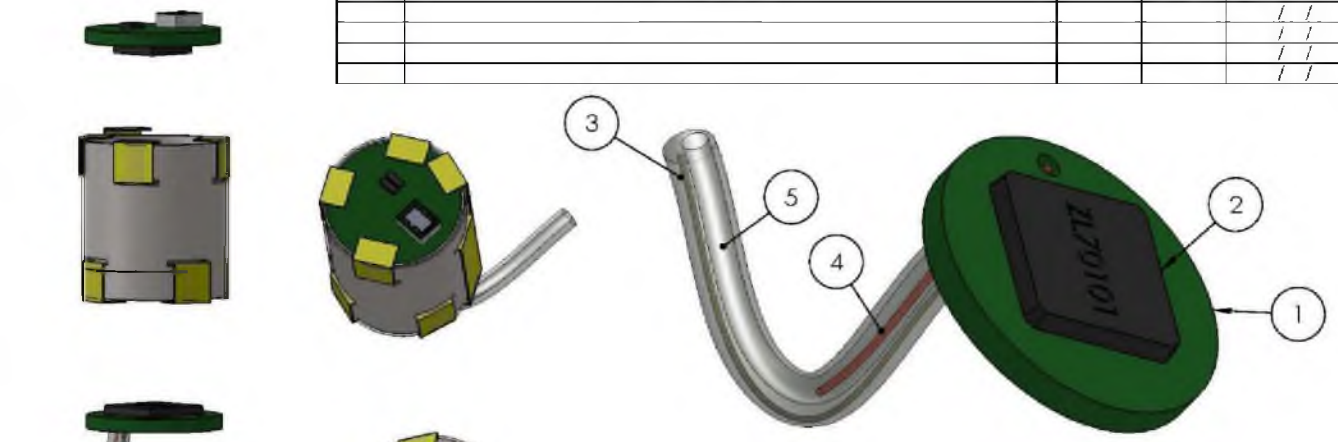

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2	019-001	ADA-0022	Zarlink ZL70101	1
3	017-001	ADA-0019	Strain Relief Tether	1
4	018-001	ADA-0020	Antenna	1
5	016-001	ADA-0018	Vent Tube	1

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

DECIMAL .X ±.25 .XX ±.01 .XXX ±.003

ANG ±1°

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T.COLEMAN	10/26/10
CHECKED	
APPROVED	

Department of Bioengineering

THE UNIVERSITY OF UTAH

IPS

THIRD ANGLE PROJECTION

MATERIAL: N/A

SPEC NO. N/A

SCALE: 2:1

DO NOT SCALE DRAWING

TITLE: WRAPS - ELECTRONICS PACKAGE BOTTOM

DWG. NO. ADA-0021

SIZE	PART/MAT'L NO.	DOC REV.
A	N/A	00

DOC NO. 1 SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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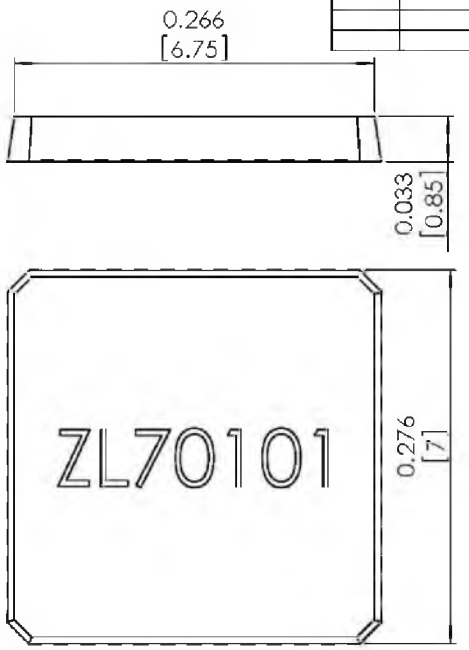

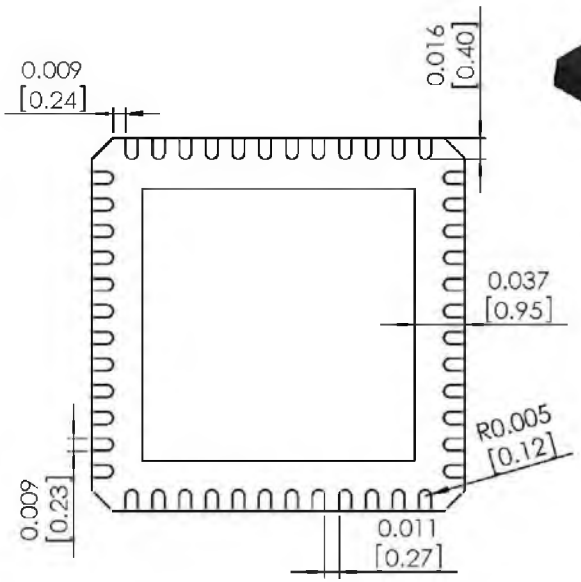

SCALE 5:1

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES	SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE	**Department of Bioengineering**	
MACHINED SURFACES DECIMAL .X ±.25 .XX ±.01 .XXX ±.003 ANG ±1°	APPROVALS / DRAWN T. COLEMAN / CHECKED / APPROVED	DATE 10/27/10	THE UNIVERSITY OF UTAH
IPS THIRD ANGLE PROJECTION	MATERIAL:		TITLE: WRAPS - WIRELESS CHIP ZL70101
	SPEC NO. N/A	SCALE: 10:1	DWG. NO. ADA-0022
		DO NOT SCALE DRAWING	SIZE A / PART/MAT'L NO. 019-001 / DOC REV. 00
			DOC NO. 1 / SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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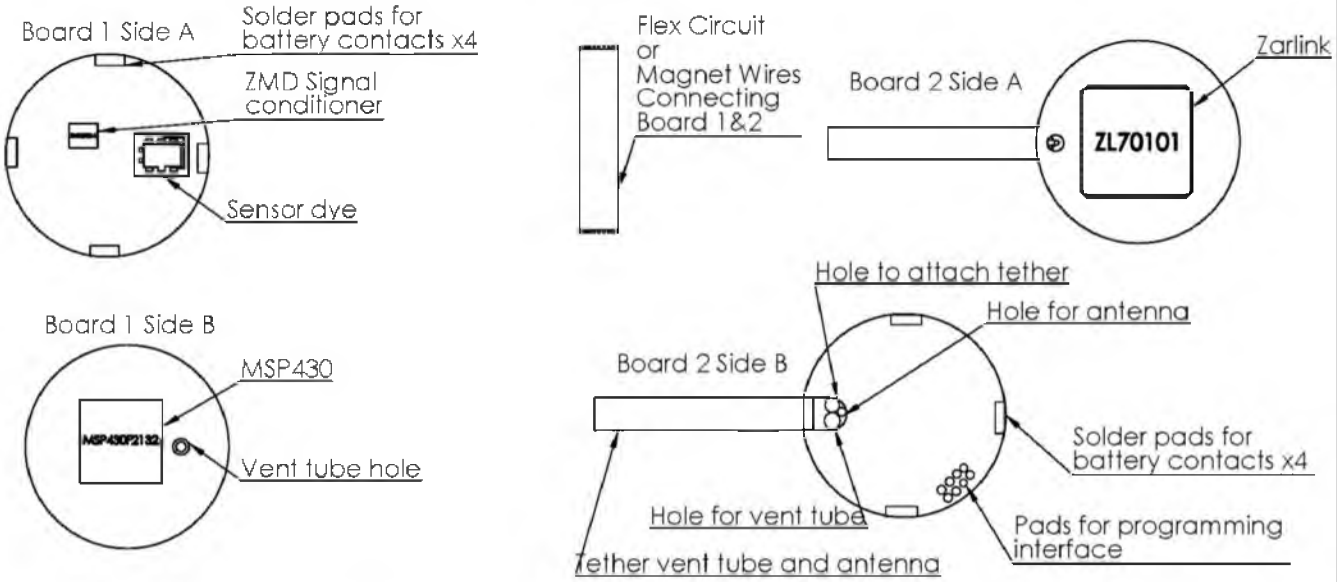

Note:

See ADA-0014 for battery contact placement

IPS

THIRD ANGLE PROJECTION

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25 .XX ±.01 .XXX ±.003

ANG ±1°

MATERIAL: N/A

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	10/13/10
CHECKED	
APPROVED	

SCALE: 3:1

DO NOT SCALE DRAWING

Department of Bioengineering

THE UNIVERSITY OF UTAH

TITLE: WRAPS - BOARD SKETCH

DWG. NO. ADA-0023

SIZE	PART/MAT'L NO.	DOC REV.
A	N/A	00

DOC NO. 1 SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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01	New Battery Size and Capacity		10/29/10	TC / /
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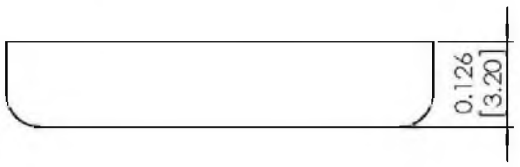

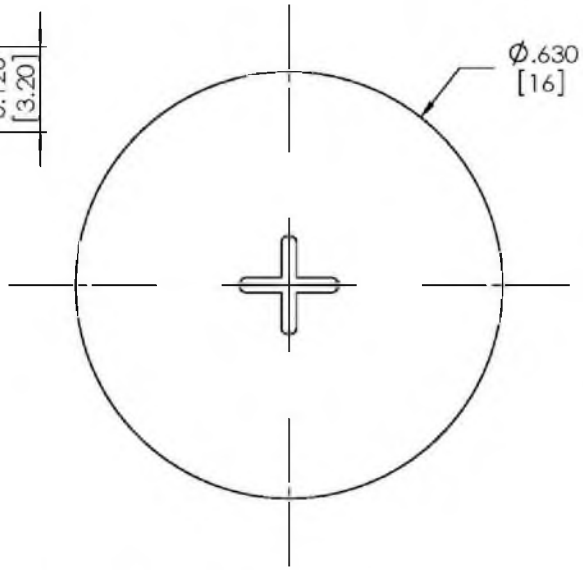

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

IPS

THIRD ANGLE PROJECTION

MATERIAL:
LITHIUM/MANGANESE DIOXIDE BATTERY

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	10/29/10
CHECKED	
APPROVED	

SCALE: 5:1

DO NOT SCALE DRAWING

Department of Bioengineering
THE UNIVERSITY OF UTAH

TITLE: WRAPS - IEC-CR1632 BATTERY

DWG. NO. ADA-0024

SIZE	PART/MAT'L NO.	DOC REV.
A	002-001	01

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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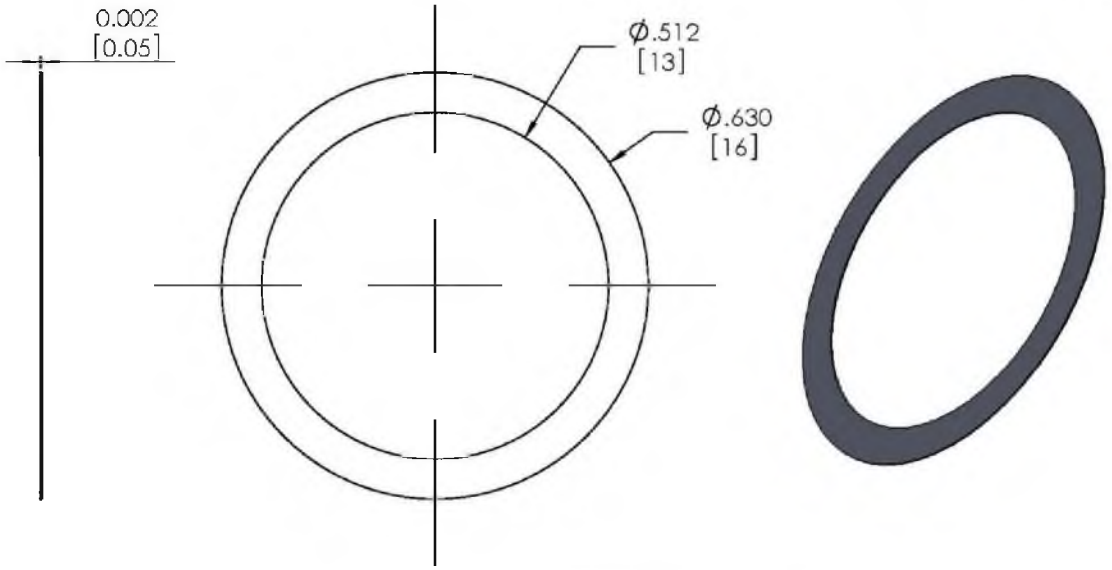

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

IPS

THIRD ANGLE PROJECTION

MATERIAL:

POLYESTER

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	10/29/10
CHECKED	
APPROVED	

SCALE: 5:1

DO NOT SCALE DRAWING

Department of Bioengineering

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TITLE: WRAPS - SHORT PROTECTOR

DWG. NO. A DA-0025

SIZE	PART/MAT'L NO.	DOC REV.
A	004-001	01

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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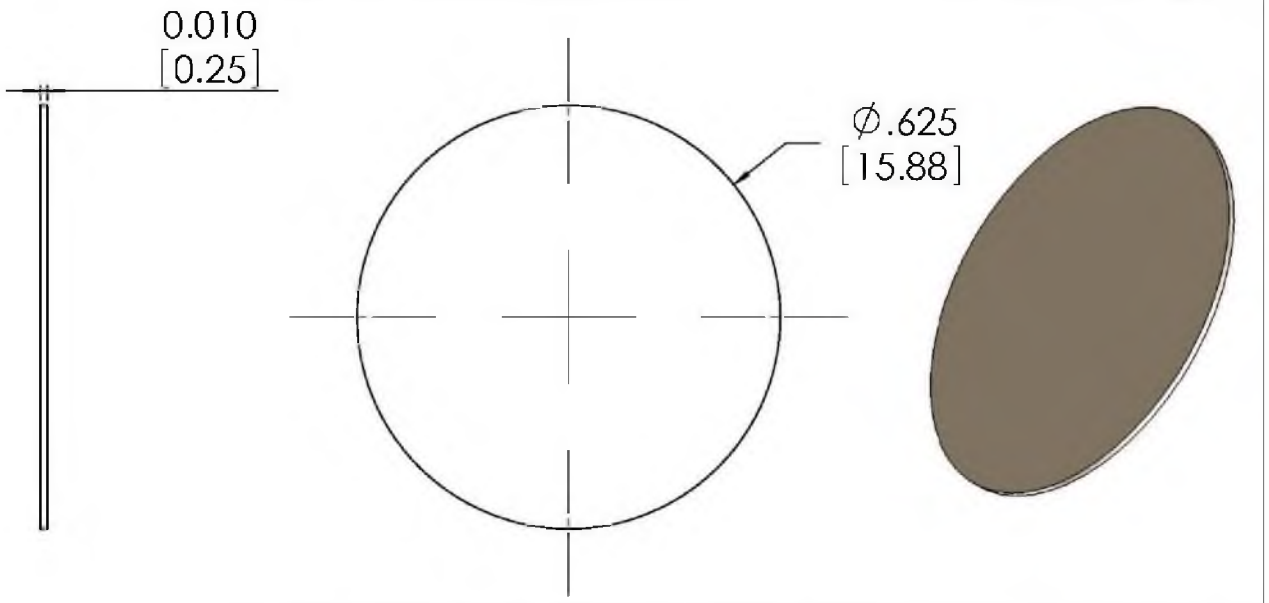

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES MACHINED SURFACES DECIMAL .X ±.25 .XX ±.01 .XXX ±.003 ANG ±1°	SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE APPROVALS / DATE DRAWN A. ACHER 10/25/10 CHECKED APPROVED	**Department of Bioengineering** THE UNIVERSITY OF UTAH
IPS THIRD ANGLE PROJECTION	MATERIAL: POLYESTER	TITLE: WRAPS -Contact Protector
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	SPEC NO. N/A	SIZE A / PART/MAT'L NO. 003-001 / DOC REV. 01
	SCALE: 5:1 DO NOT SCALE DRAWING	DOC NO. 1 / SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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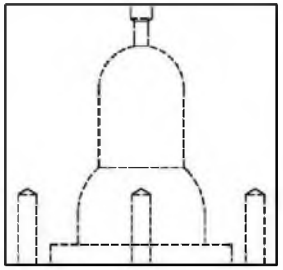
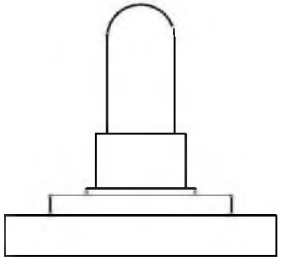
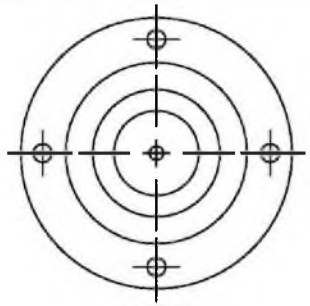
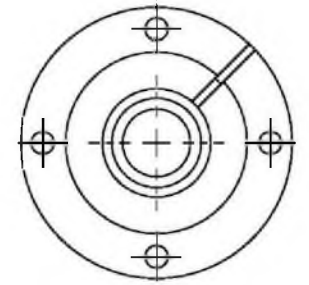
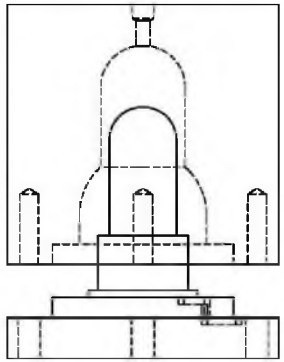






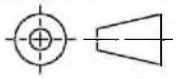




SCALE 1:2

IPS

THIRD ANGLE PROJECTION



UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.05
.XX ±.01
.XXX ±.005

ANG ±1°

MATERIAL:

ALUMINUM

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	10/28/10
CHECKED	
APPROVED	

SCALE: 8:7

DO NOT SCALE DRAWING

Department of Bioengineering

THE UNIVERSITY OF UTAH

TITLE: WRAPS - INJECTION MOLD ASSEMBLY

DWG. NO. ADA-0027

SIZE	PART/MAT'L NO.	DOC REV.
A	N/A	00

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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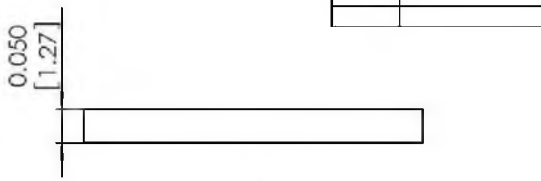

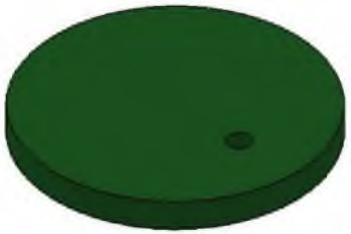

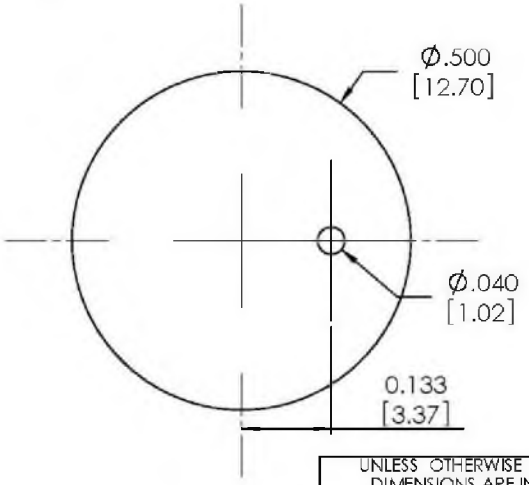

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

IPS

THIRD ANGLE PROJECTION

MATERIAL:
SILICON

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	10/26/10
CHECKED	
APPROVED	

SCALE: 5:1

DO NOT SCALE DRAWING

Department of Bioengineering
THE UNIVERSITY OF UTAH

TITLE: WRAPS - IMD CIRCUIT BOARD

DWG. NO. ADA-0028

SIZE	PART/MAT'L NO.	DOC REV.
A	008-001	00

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
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				/ /
				/ /
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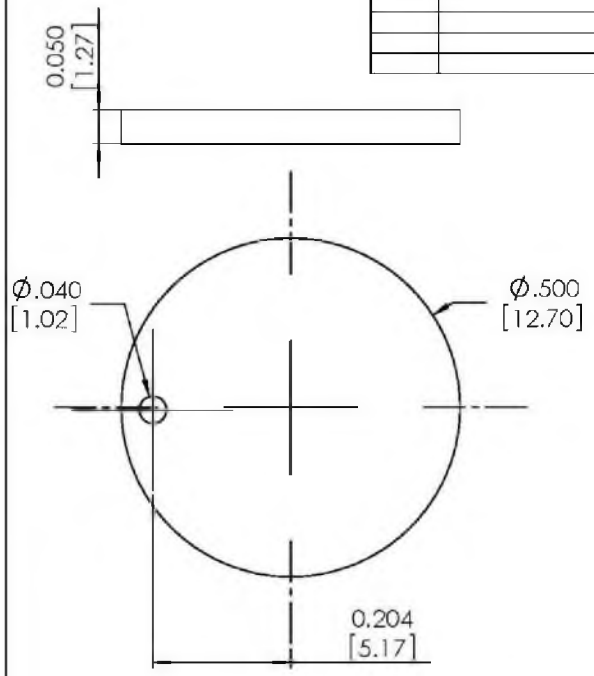

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

IPS

THIRD ANGLE PROJECTION

MATERIAL: SILICON

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	10/26/10
CHECKED	
APPROVED	

SCALE: 5:1

DO NOT SCALE DRAWING

Department of Bioengineering

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TITLE: WRAPS - RF CIRCUIT BOARD

DWG. NO. ADA-0029

SIZE	PART/MAT'L NO.	DOC REV.
A	009-001	00

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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01	DIMENTION AND FEATURE CHANGE		11/29/10	TC / /
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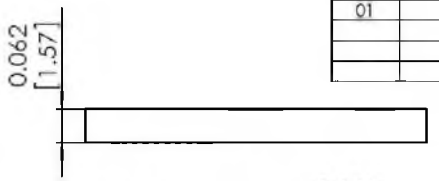
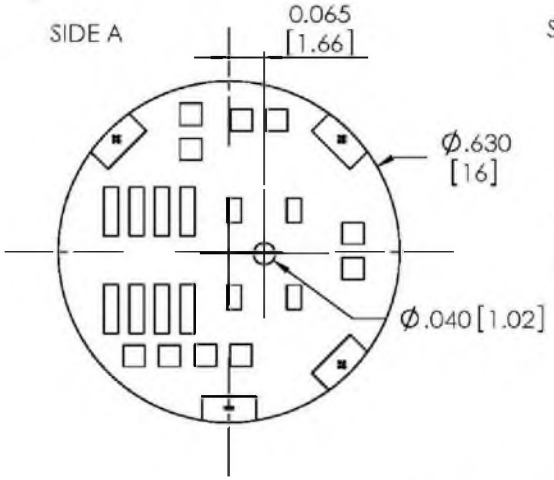
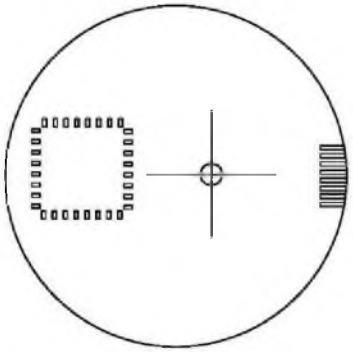
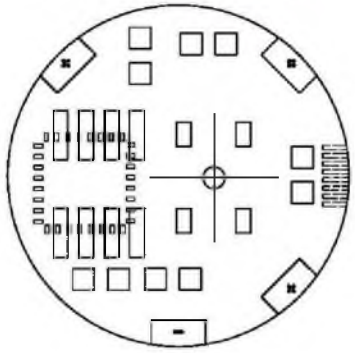


SCALE 2:1







UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES	SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE	**Department of Bioengineering**	
DECIMAL .X ±.25 .XX ±.01 .XXX ±.003 ANG ±1°	APPROVALS / DRAWN T. COLEMAN / CHECKED / APPROVED	DATE 10/26/10	THE UNIVERSITY OF UTAH
IPS THIRD ANGLE PROJECTION	MATERIAL: SILICON	THIS DOCUMENT IS THE CONFIDENTIAL AND PROPRIETARY PROPERTY OF THE UNIVERSITY OF UTAH. REPRODUCTION, RELEASE, OR REVISION WITHOUT EXPRESS PERMISSION IS STRICTLY PROHIBITED AND MAY RESULT IN CIVIL AND CRIMINAL PENALTIES. COPYRIGHT 2010, UNIVERSITY OF UTAH. ALL RIGHTS RESERVED.	TITLE: WRAPS - IMD CIRCUIT BOARD
	SPEC NO. N/A	SCALE: 4:1	DWG. NO. ADA-0030
		DO NOT SCALE DRAWING	SIZE A / PART/MAT'L NO. 008-001 / DOC REV. 01
			DOC NO. 1 / SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
00	INITIAL RELEASE		10/26/10	TC / /
01	DIMENTION AND FEATURE CHANGE		11/29/10	TC / /
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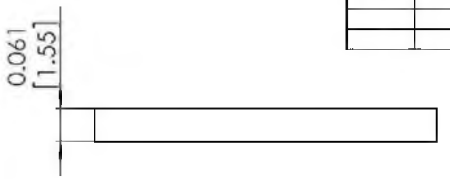
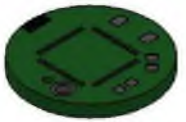
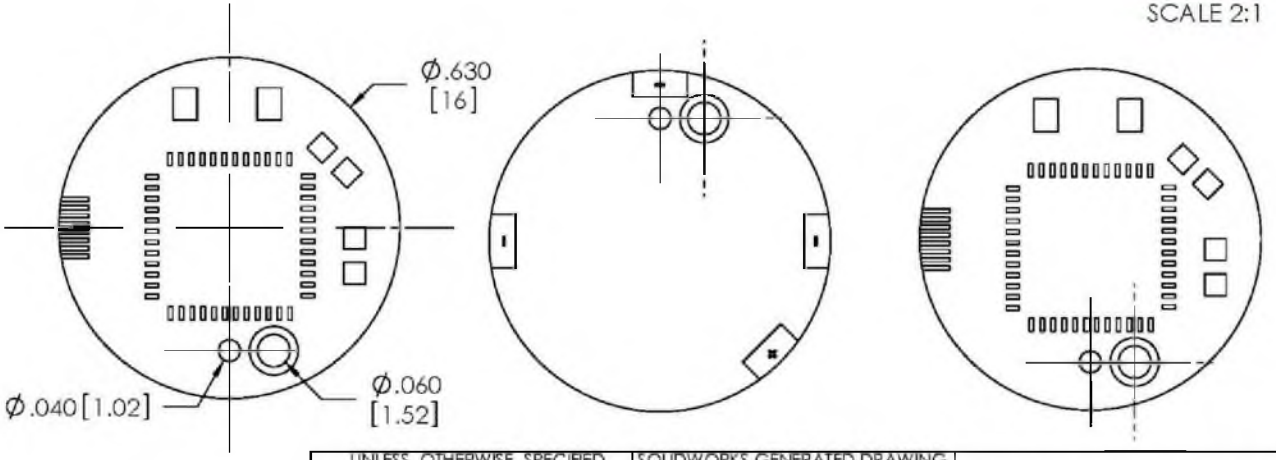
				/ /
				/ /





SCALE 2:1



UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.25
.XX ±.01
.XXX ±.003

ANG ±1°

IPS

THIRD ANGLE PROJECTION

MATERIAL:
SILICON

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	10/26/10
CHECKED	
APPROVED	

SCALE: 4:1

DO NOT SCALE DRAWING

Department of Bioengineering
THE UNIVERSITY OF UTAH

TITLE: WRAPS - RF CIRCUIT BOARD

DWG. NO. ADA-0031

SIZE	PART/MAT'L NO.	DOC REV.
A	009-001	01

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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01	DIMENTION CHANGE		11/30/10	TC / /
				/ /
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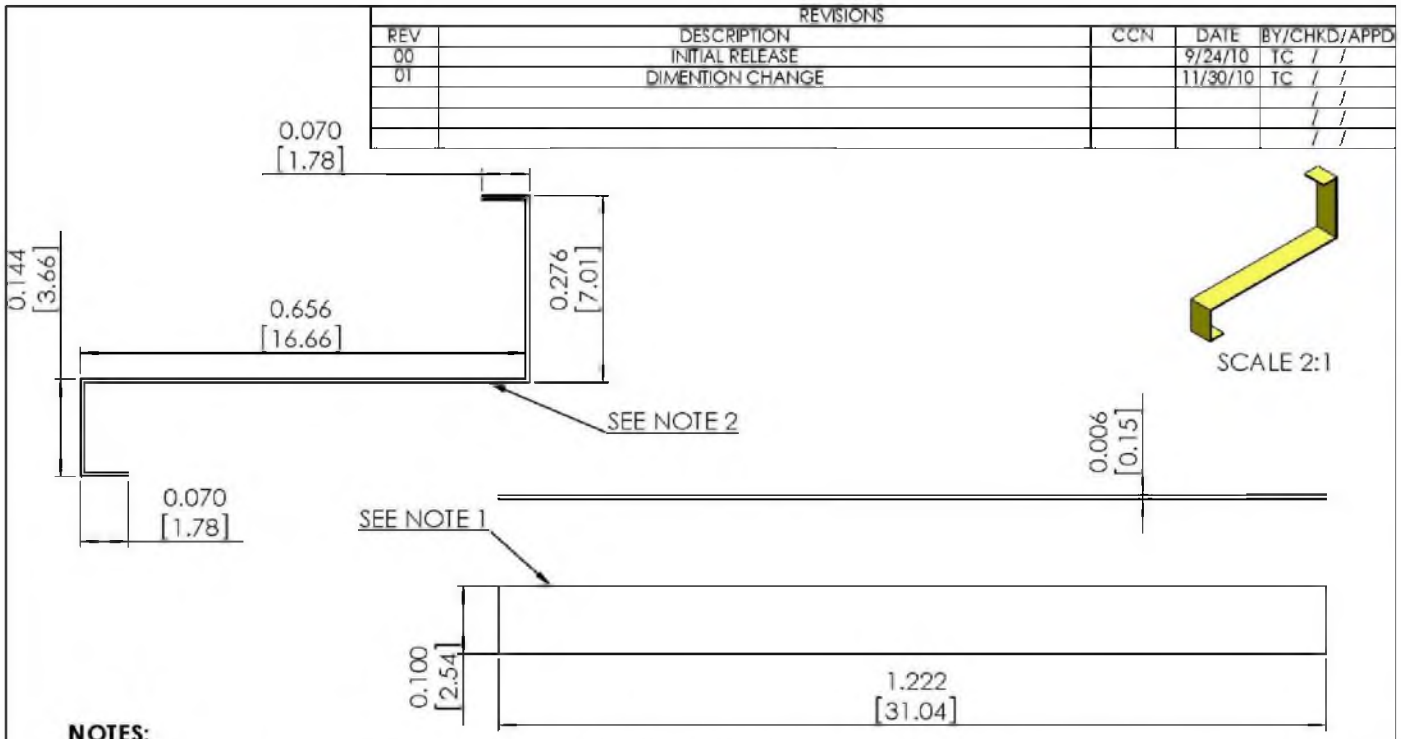
				/ /



SCALE 2:1

NOTES:

1) PART IS CUT FLAT

2) PART IS BENT TO FIT ONCE ASSEMBLED

IPS

THIRD ANGLE PROJECTION

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.05
.XX ±.01
.XXX ±.005

ANG ±1°

MATERIAL:
BRASS SHIM STOCK

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	11/30/10
CHECKED	
APPROVED	

SCALE: 5:1

DO NOT SCALE DRAWING

Department of Bioengineering
THE UNIVERSITY OF UTAH

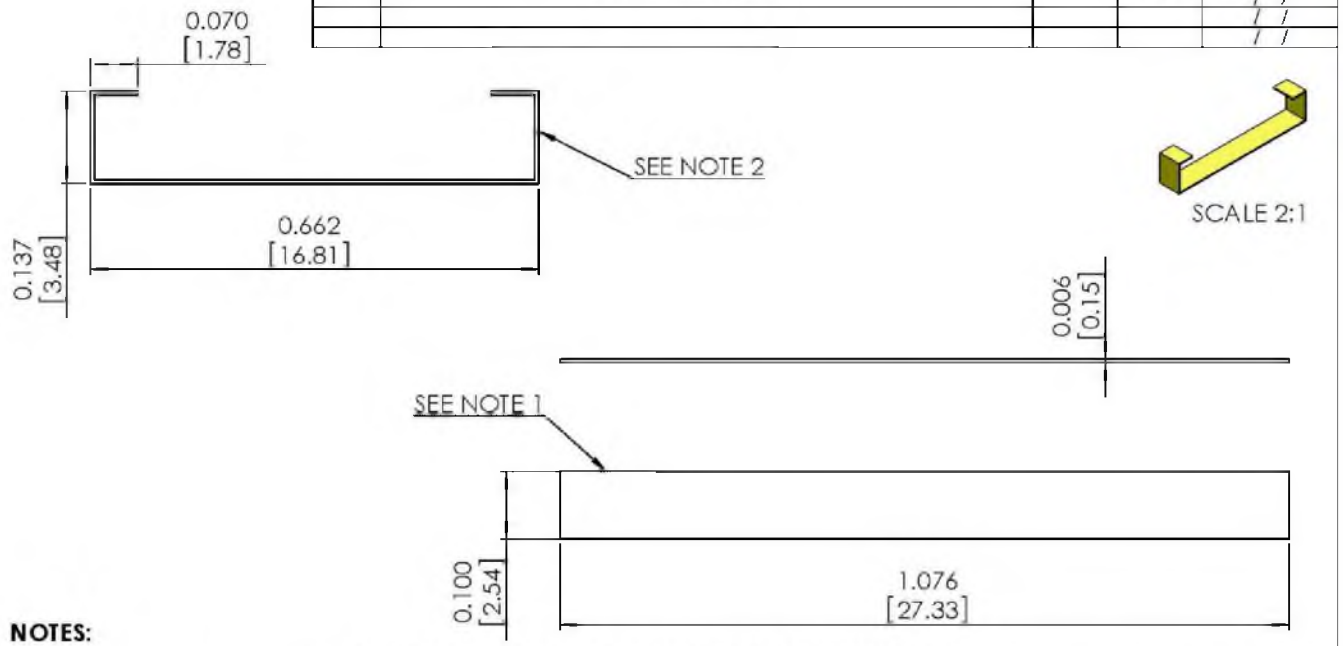
TITLE:
WRAPS - BATTERY CONTACT LONG

DWG. NO.
ADA-0032

SIZE	PART/MAT'L NO.	DOC REV.
A	006-001	01

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
00	INITIAL RELEASE		9/24/10	TC / /
01	DIMENTION CHANGE		11/30/10	TC / /
				/ /
				/ /
				/ /



NOTES:

1) PART IS CUT FLAT

2) PART IS BENT TO FIT ONCE ASSEMBLED

IPS

THIRD ANGLE PROJECTION

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.05
.XX ±.01
.XXX ±.005

ANG ±1°

MATERIAL: BRASS SHIM STOCK

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	11/30/10
CHECKED	
APPROVED	

SCALE: 5:1

DO NOT SCALE DRAWING

Department of Bioengineering

THE UNIVERSITY OF UTAH

TITLE: WRAPS - BATTERY CONTACT SHORT

DWG. NO. ADA-0033

SIZE	PART/MAT'L NO.	DOC REV.
A	005-001	01

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
00	INITIAL RELEASE		11/30/10	TC / /
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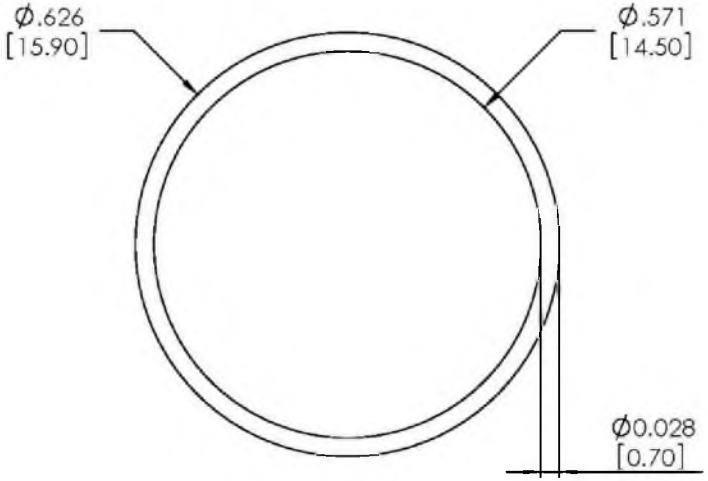
				/ /
				/ /
				/ /



UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.05
.XX ±.01
.XXX ±.005

ANG ±1°

IPS

THIRD ANGLE PROJECTION

MATERIAL:
FLUOROSILICONE

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	11/30/10
CHECKED	
APPROVED	

SCALE: 5:1

DO NOT SCALE DRAWING

Department of Bioengineering
THE UNIVERSITY OF UTAH

TITLE: WRAPS - O-RING

DWG. NO. ADA-0034

SIZE	PART/MAT'L NO.	DOC REV.
A	020-001	00

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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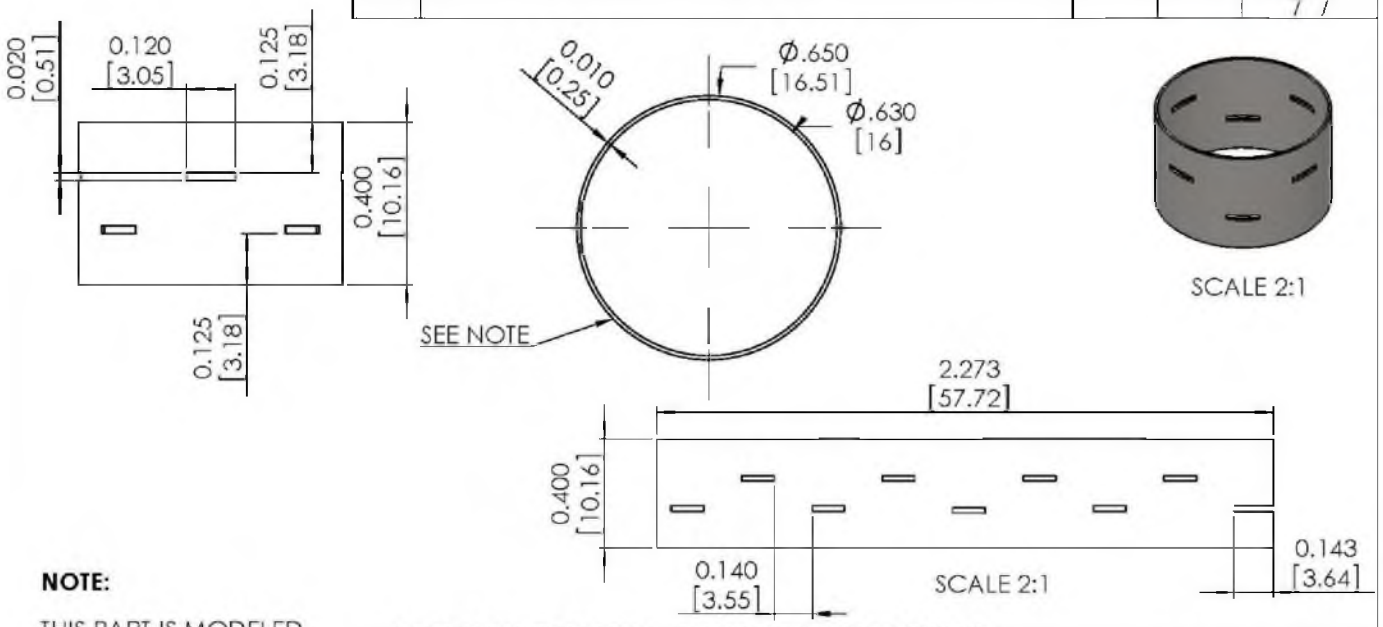
01	DIMENTION CHANGE		11/30/10	TC / /
				/ /
				/ /
				/ /



NOTE:

THIS PART IS MODELED FROM FLAT PART

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES	SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE	**Department of Bioengineering**	
MACHINED SURFACES DECIMAL .X ±.05 .XX ±.01 .XXX ±.005 ANG ±1°	APPROVALS / DRAWN T. COLEMAN / CHECKED / APPROVED	DATE 11/30/10	THE UNIVERSITY OF UTAH
IPS THIRD ANGLE PROJECTION	MATERIAL: POLYESTER		TITLE: WRAPS - BATTERY PROTECTOR
	SPEC NO. N/A	SCALE: 3:1	DWG. NO. ADA-0035
		DO NOT SCALE DRAWING	SIZE A / PART/MAT'L NO. 000-001 / DOC REV. 01
			DOC NO. 1 / SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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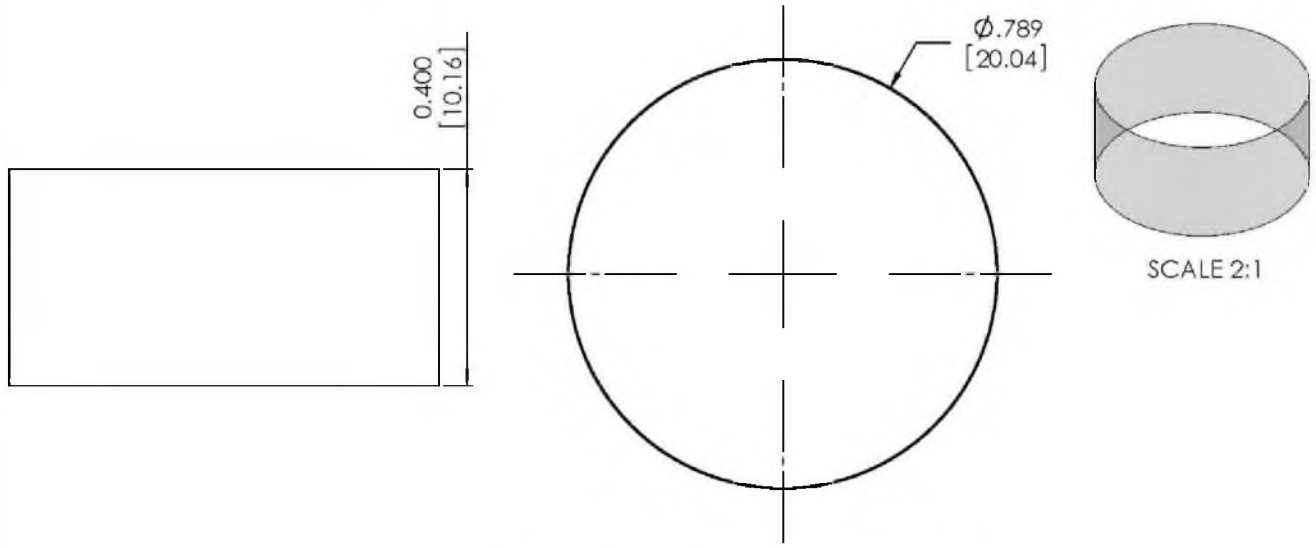
01	DIMENTION CHANGE		11/30/10	TC / /
				/ /
				/ /
				/ /



UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.05
.XX ±.01
.XXX ±.005

ANG ±1°

IPS

THIRD ANGLE PROJECTION

MATERIAL:
CLEAR POLYESTER

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	11/30/10
CHECKED	
APPROVED	

SCALE: 4:1

DO NOT SCALE DRAWING

Department of Bioengineering
THE UNIVERSITY OF UTAH

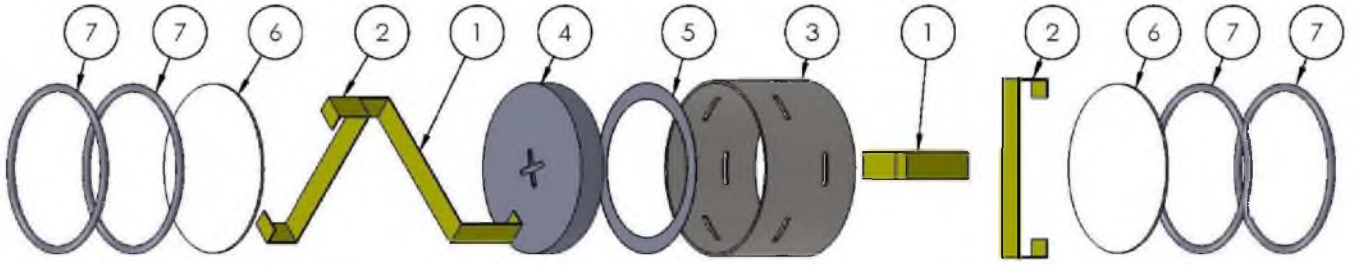
TITLE: WRAPS - SHRINK TUBING

DWG. NO. ADA-0036

SIZE	PART/MAT'L NO.	DOC REV.
A	007-001	01

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
00	INITIAL RELEASE		9/23/10	TC / /
01	DIMENTION AND COMPOSITION CHANGE		11/30/10	TC / /
				/ /
				/ /
				/ /



ITEM NO.	PART NO.	DWG. [REF. ONLY]	DESCRIPTION	QTY.
1	006-001	ADA-0032	Battery Contact Long	2
2	005-001	ADA-0033	Battery Contact Short	2
3	000-001	ADA-0035	Battery Protector	1
4	002-001	ADA-0024	CR1632 Battery	1
5	004-001	ADA-0025	Short Protector	1
6	003-001	ADA-0026	Contact Protector	2
7	020-001	ADA-0034	O-Ring	4

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.05
.XX ±.01
.XXX ±.005

ANG ±1°

IPS

THIRD ANGLE PROJECTION

MATERIAL:

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	11/30/10
CHECKED	
APPROVED	

SCALE: 2:1

DO NOT SCALE DRAWING

Department of Bioengineering

THE UNIVERSITY OF UTAH

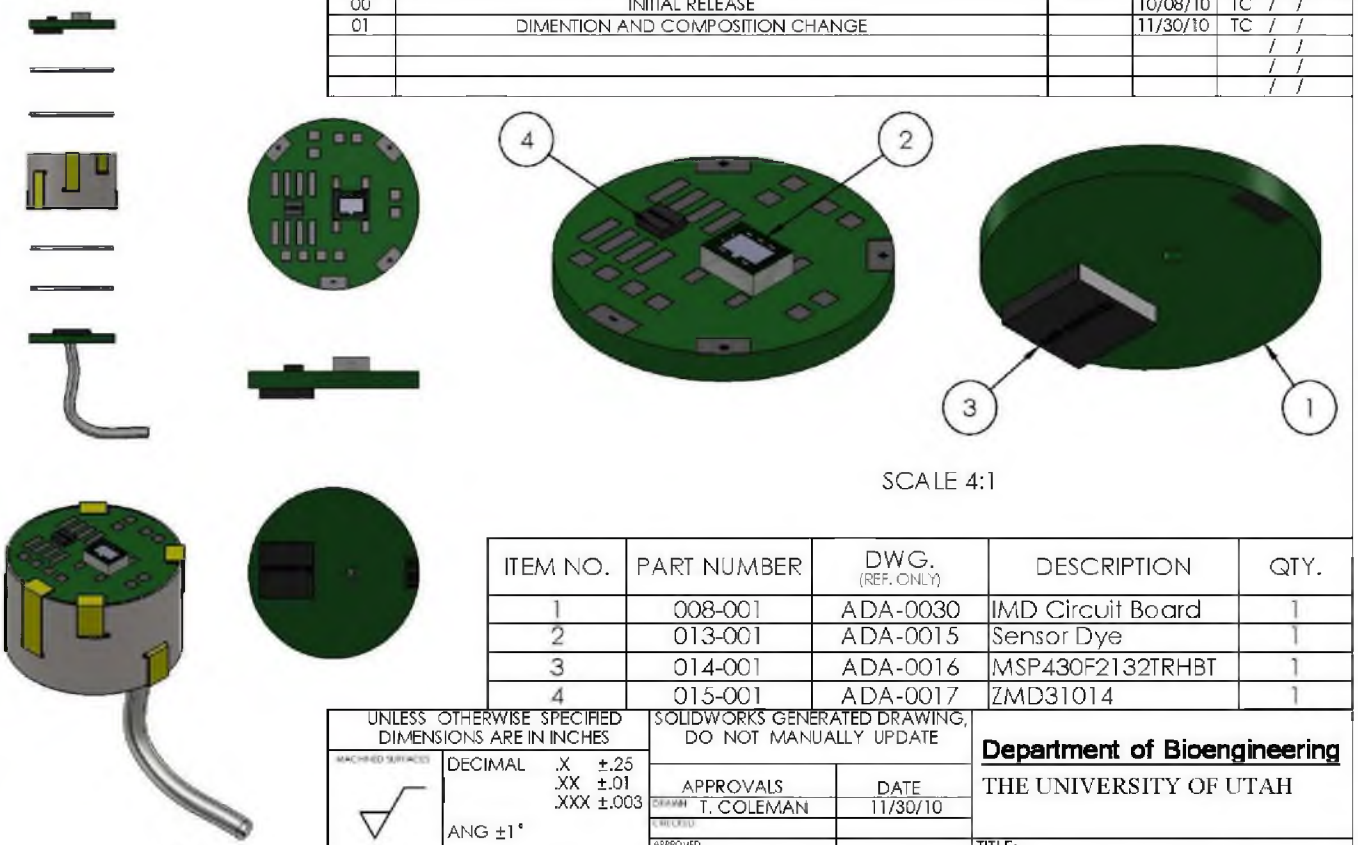
TITLE: WRAPS - BATTERY PACKAGE

DWG. NO. ADA-0037

SIZE	PART/MAT'L NO.	DOC REV.
A	SEE SPEC.	01

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
00	INITIAL RELEASE		10/08/10	TC / /
01	DIMENTION AND COMPOSITION CHANGE		11/30/10	TC / /
				/ /
				/ /
				/ /



SCALE 4:1

ITEM NO.	PART NUMBER	DWG. (REF. ONLY)	DESCRIPTION	QTY.
1	008-001	ADA-0030	IMD Circuit Board	1
2	013-001	ADA-0015	Sensor Dye	1
3	014-001	ADA-0016	MSP430F2132TRHBT	1
4	015-001	ADA-0017	ZMD31014	1

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

DECIMAL .X ±.25 .XX ±.01 .XXX ±.003

ANG ±1°

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	11/30/10
CHECKED	
APPROVED	

Department of Bioengineering
THE UNIVERSITY OF UTAH

IPS

THIRD ANGLE PROJECTION

MATERIAL: N/A

SPEC NO. N/A

SCALE: 2:1

DO NOT SCALE DRAWING

TITLE: WRAPS - ELECTRONICS PACKAGE TOP

DWG. NO. ADA-0038

SIZE	PART/MAT'L NO.	DOC REV.
A	N/A	01

DOC NO. 1 SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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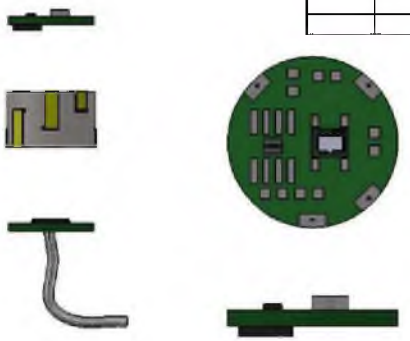
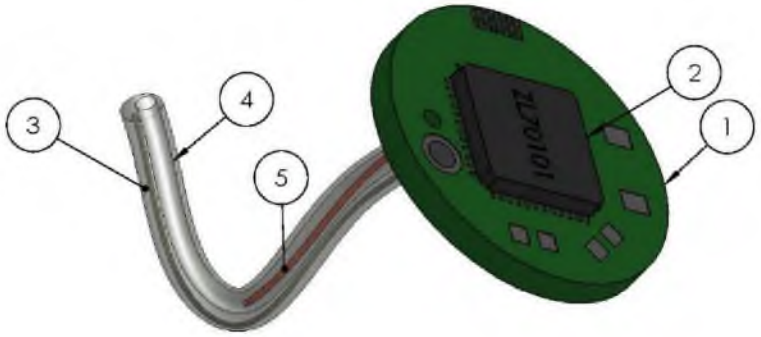
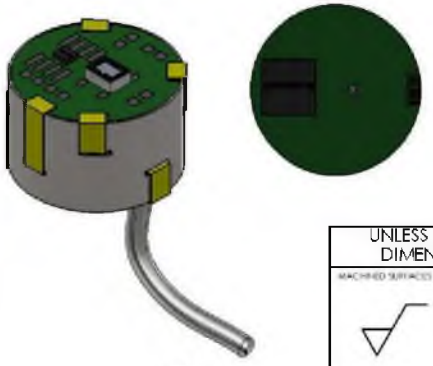
01	DIMENTION AND COMPOSITION CHANGE		11/30/10	TC / /
				/ /
				/ /
				/ /







ITEM NO.	PART NO.	DWG. (REF. ONLY)	DESCRIPTION	QTY.
1	008-001	ADA-031	RF Circuit Board	1
2	019-001	ADA-0022	Zarlink ZL70101	1
3	017-001	ADA-0019	Strain Relief Tether	1
4	016-001	ADA-0018	Vent Tube	1
5	018-001	ADA-0020	Antenna	1

IPS

THIRD ANGLE PROJECTION

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

DECIMAL .X ±.25 .XX ±.01 .XXX ±.003

ANG ±1°

MATERIAL: N/A

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	11/30/10
CHECKED	
APPROVED	

SCALE: 2:1

DO NOT SCALE DRAWING

Department of Bioengineering

THE UNIVERSITY OF UTAH

TITLE: WRAPS - ELECTRONICS PACKAGE BOTTOM

DWG. NO. ADA-0039

SIZE	PART/MAT'L NO.	DOC REV.
A	N/A	01

DOC NO. 1 | SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
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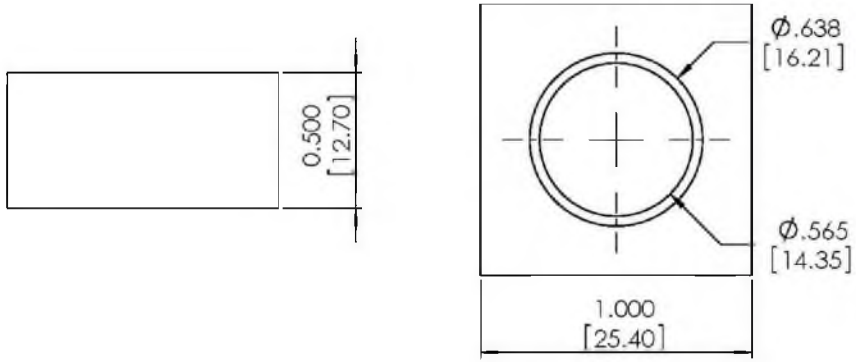
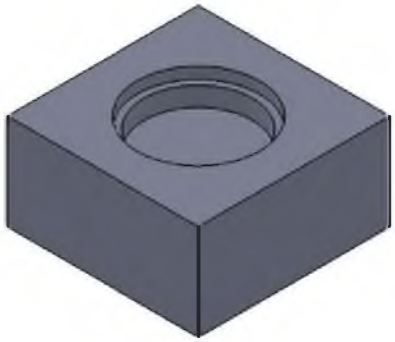
				/ /
				/ /
				/ /





UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.05
.XX ±.01
.XXX ±.005

ANG ±1°

IPS

THIRD ANGLE PROJECTION

MATERIAL:
POLYCARBONATE

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	12/16/10
CHECKED	
APPROVED	

SCALE: 2:1

DO NOT SCALE DRAWING

Department of Bioengineering
THE UNIVERSITY OF UTAH

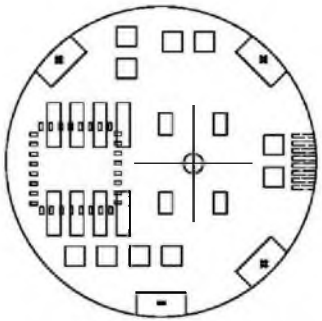
TITLE:
WRAPS - CIRCUIT BOARD HOLDER

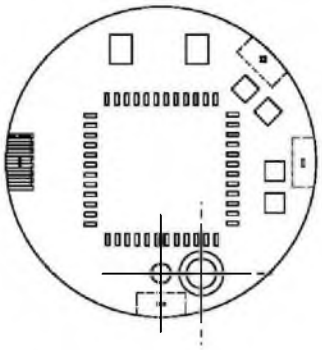
DWG. NO.
ADA-0040

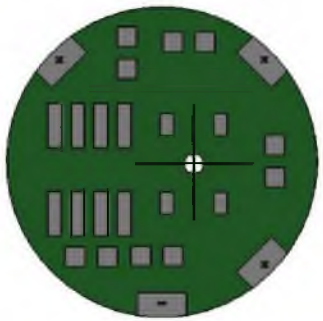
SIZE	PART/MAT'L NO.	DOC REV.
A	021-001	00

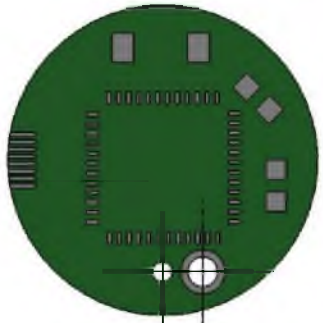
DOC NO. 1 | SHEET 1 OF 1

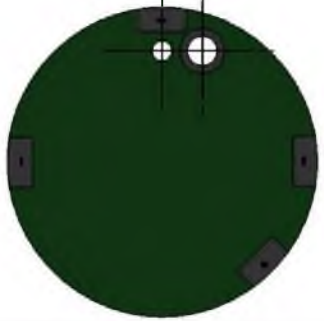
REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
00	INITIAL RELEASE		1/18/11	TC / /
				/ /







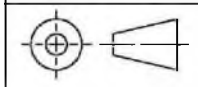




UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES	SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE	Department of Bioengineering
DECIMAL .X ±.05 .XX ±.01 .XXX ±.005 ANG ±1°	APPROVALS / DATE DRAWN T. COLEMAN 1/18/11 CHECKED APPROVED	THE UNIVERSITY OF UTAH
MATERIAL:		TITLE: WRAPS -CIRCUIT BOARDS
		DWG. NO. ADA-0041
SPEC NO. N/A	SCALE: 4:1.1	SIZE A / PART/MAT'L NO. N/A / DOC REV. 00
	DO NOT SCALE DRAWING	DOC NO. 1 / SHEET 1 OF 1

IPS

THIRD ANGLE PROJECTION



REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
00	INITIAL RELEASE		1/25/11	TC / /
				/ /
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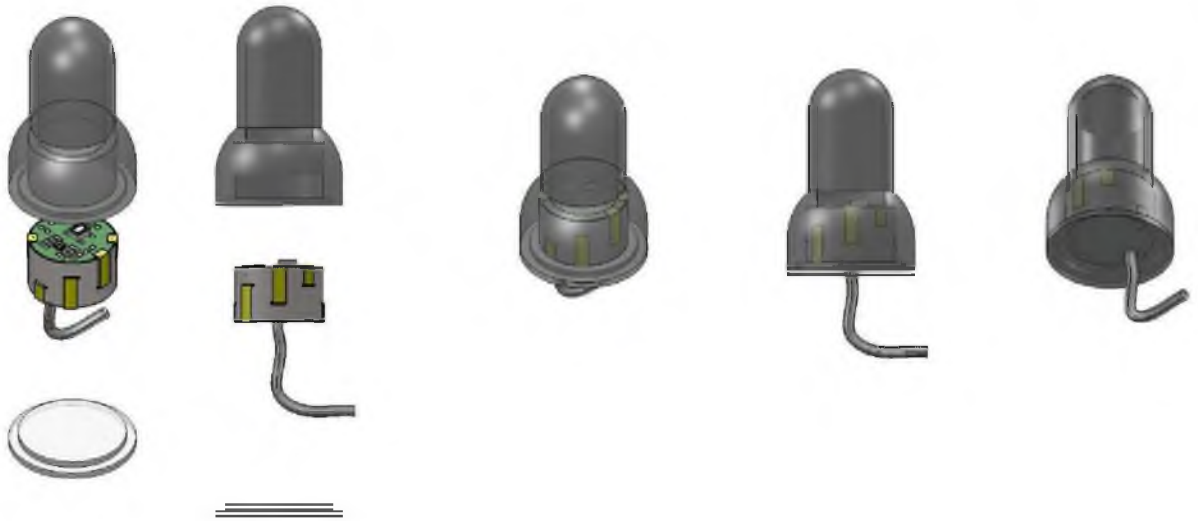
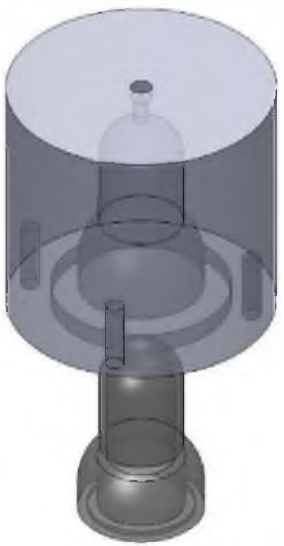
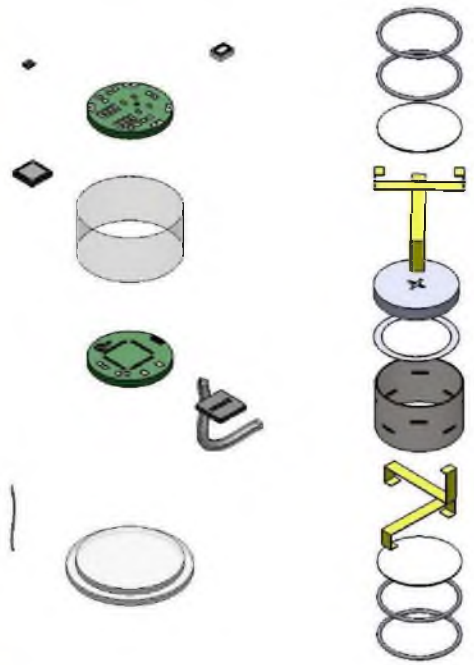


UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES	SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE	**Department of Bioengineering**	
MACHINED SURFACES DECIMAL .X ±.05 .XX ±.01 .XXX ±.005 ANG ±1°	APPROVALS / DRAWN T. COLEMAN / APPROVED	DATE 1/25/11	THE UNIVERSITY OF UTAH
IPS THIRD ANGLE PROJECTION	MATERIAL:	THIS DOCUMENT IS THE CONFIDENTIAL AND PROPRIETARY PROPERTY OF THE UNIVERSITY OF UTAH. REPRODUCTION, RELEASE, OR REVISION WITHOUT EXPRESS PERMISSION IS STRICTLY PROHIBITED AND MAY RESULT IN CIVIL AND CRIMINAL PENALTIES. COPYRIGHT 2010, UNIVERSITY OF UTAH. ALL RIGHTS RESERVED.	TITLE: WRAPS - COMPLETE ASSEMBLY
	SPEC NO. N/A	SCALE: 1:1	DWG. NO. ADA-0042
		DO NOT SCALE DRAWING	SIZE A / PART/MAT'L NO. N/A / DOC REV. 00
			DOC NO. 1 / SHEET 1 OF 1





REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
00	INITIAL RELEASE		1/25/11	TC / /

IPS

THIRD ANGLE PROJECTION

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.05
.XX ±.01
.XXX ±.005

ANG ±1°

MATERIAL:

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	1/25/11
CHECKED	
APPROVED	

SCALE: 1:1

DO NOT SCALE DRAWING

Department of Bioengineering

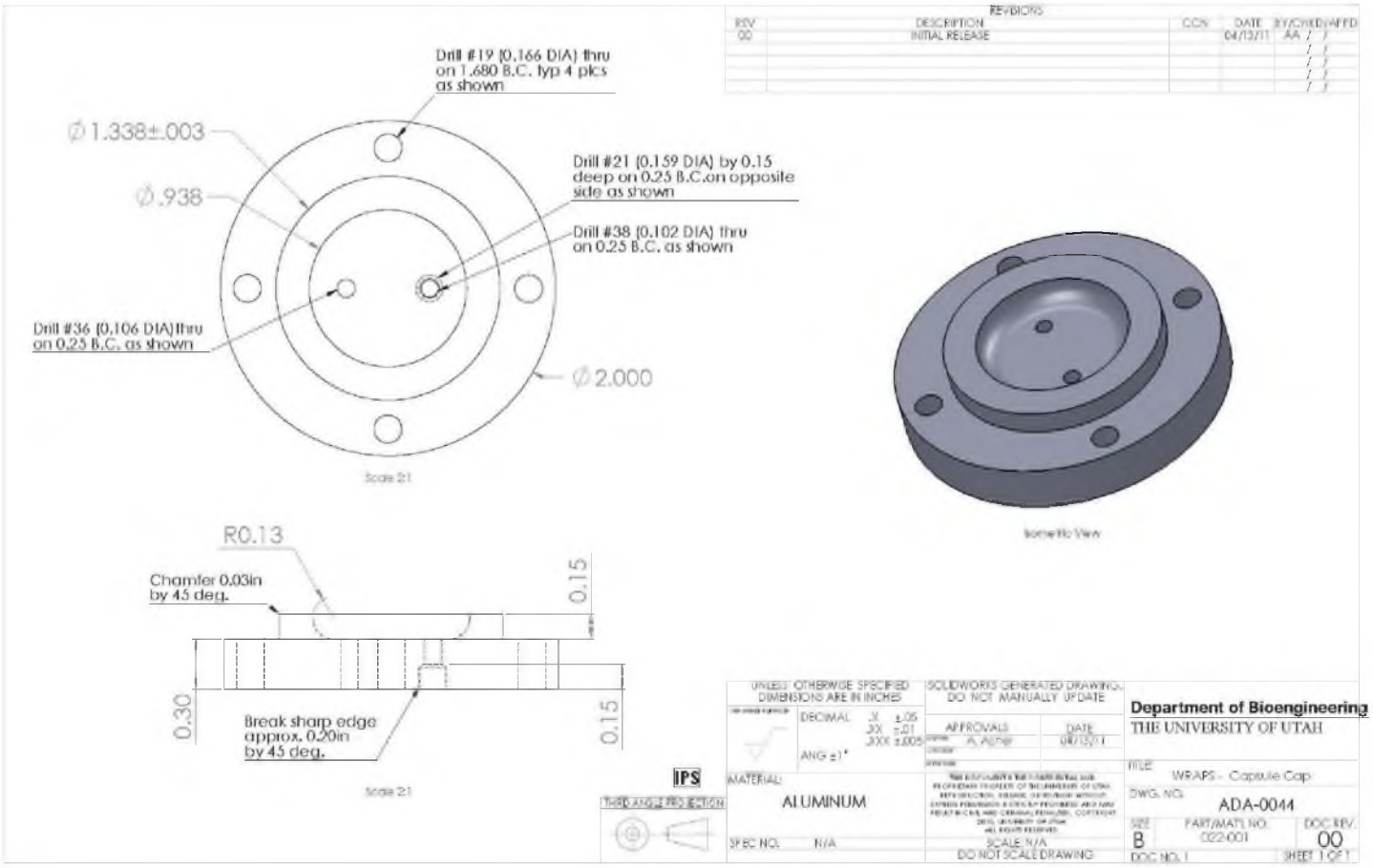
THE UNIVERSITY OF UTAH

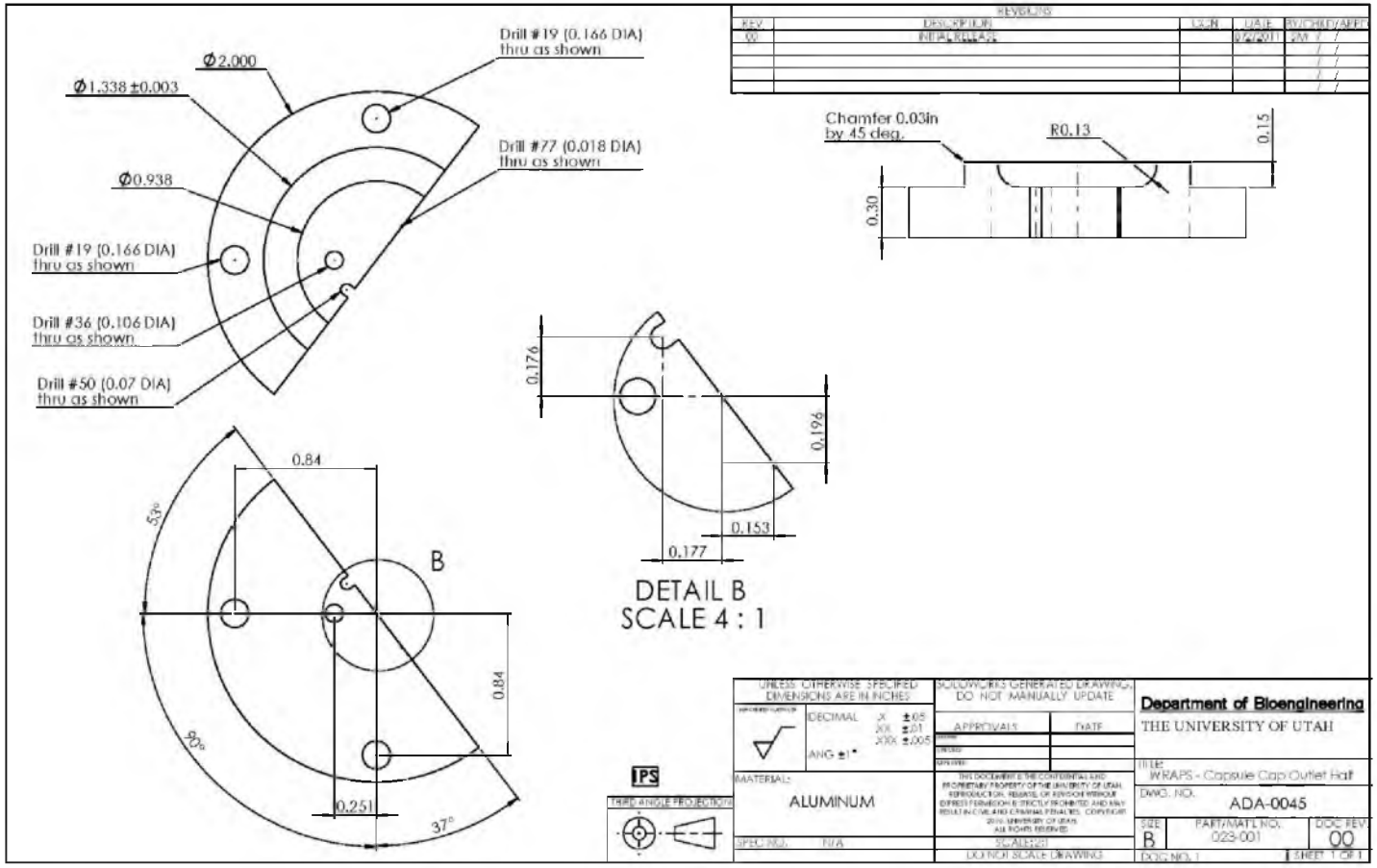
TITLE: WRAPS - MASTER ASSEMBLY

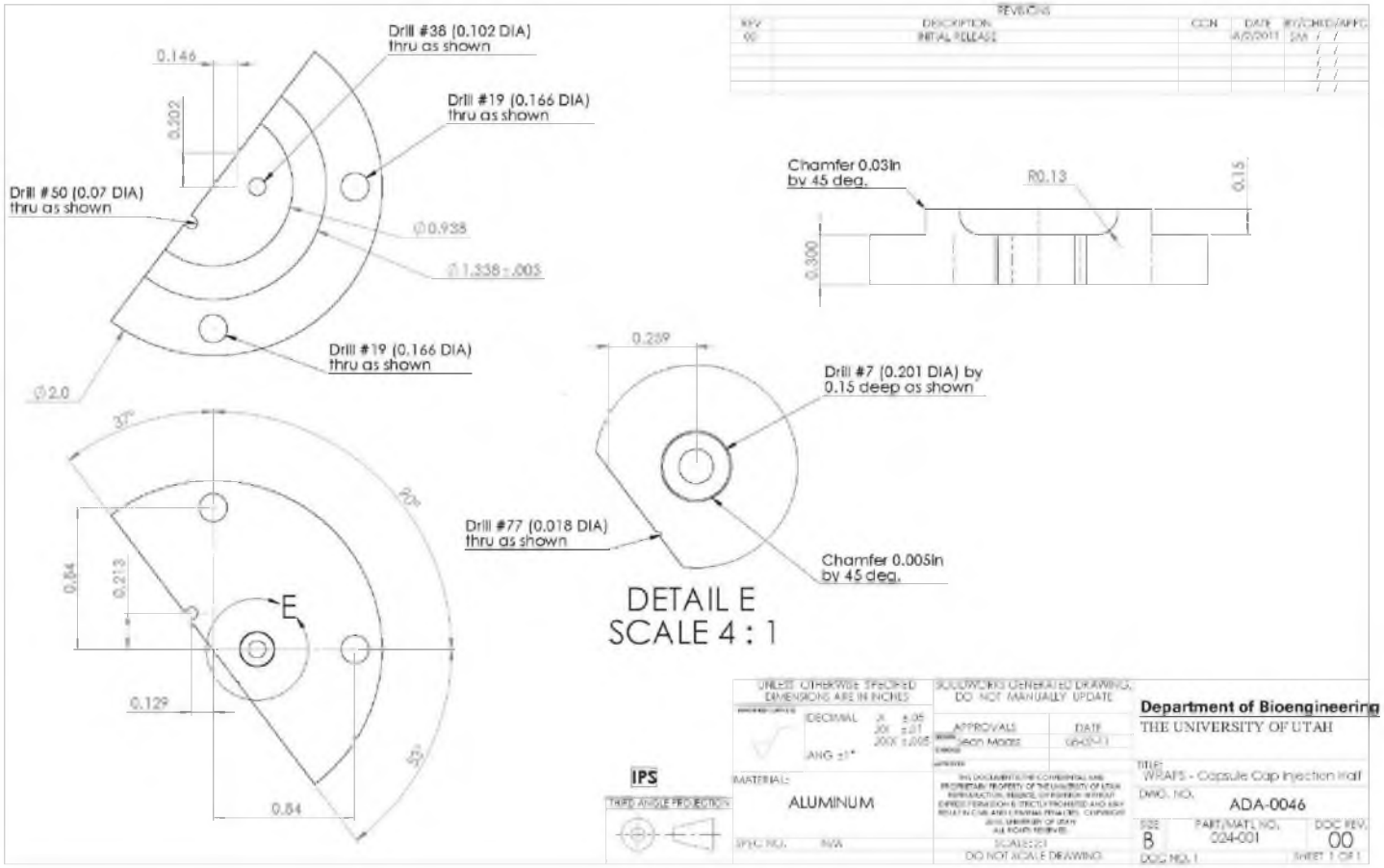
DWG. NO. A DA-0043

SIZE	PART/MAT'L NO.	DOC REV.
A	N/A	00

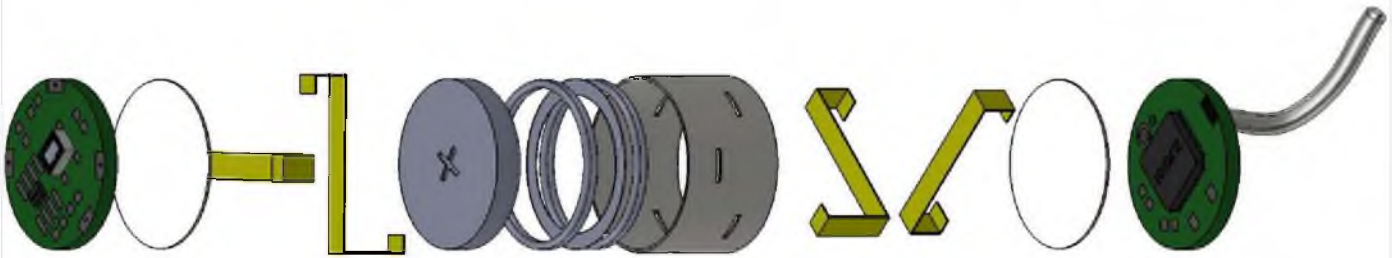
DOC NO. 1 | SHEET 1 OF 1

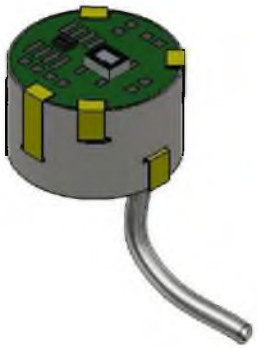

REVISIONS
REV DESCRIPTION ECN DATE BY/CHKD/APPD
00 INITIAL RELEASE 04/13/11 AA / /
Drill #19 (0.166 DIA) thru on 1.680 B.C. typ 4 plcs as shown
Ø1.338±.003
Ø.938
Drill #21 (0.159 DIA) by 0.15 deep on 0.25 B.C.on opposite side as shown
Drill #38 (0.102 DIA) thru on 0.25 B.C. as shown
Drill #36 (0.106 DIA) thru on 0.25 B.C. as shown
Ø2.000
Scale 2:1
Isometric View
R0.13
Chamfer 0.03in by 45 deg.
0.15
0.30
0.15
Break sharp edge approx. 0.20in by 45 deg.
Scale 2:1
UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES
DECIMAL .X ±.05 .XX ±.01 .XXX ±.005
ANG ±1°
SOLIDWORKS GENERATED DRAWING. DO NOT MANUALLY UPDATE
APPROVALS DATE
A. Archer 04/13/11
Department of Bioengineering
THE UNIVERSITY OF UTAH
TITLE: WRAPS - Capsule Cap
DWG. NO. ADA-0044
SIZE B PART/MAT'L NO. 022-001 DOC REV. 00
DOC NO. 1 SHEET 1 OF 1
IPS
THIRD ANGLE PROJECTION
MATERIAL: ALUMINUM
SPEC NO. N/A
SCALE: N/A
DO NOT SCALE DRAWING


REVISIONS
REV
DESCRIPTION
DATE
BY/CHKD/APPD
00
INITIAL RELEASE
8/24/2011
ZM
Drill #19 (0.166 DIA) thru as shown
Ø2.000
Ø1.338 ±0.003
Drill #77 (0.018 DIA) thru as shown
Ø0.938
Drill #19 (0.166 DIA) thru as shown
Drill #36 (0.106 DIA) thru as shown
Drill #50 (0.07 DIA) thru as shown
Chamfer 0.03in by 45 deg.
R0.13
0.15
0.30
0.176
0.196
0.153
0.177
DETAIL B
SCALE 4 : 1
0.84
53°
B
0.84
90°
0.251
37°
UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES
DECIMAL X ±.05 XX ±.01 XXX ±.005
ANG ±1°
MATERIAL:
ALUMINUM
SPEC NO.: N/A
SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE
APPROVALS
DATE
THIRD ANGLE PROJECTION
DO NOT SCALE DRAWING
Department of Bioengineering
THE UNIVERSITY OF UTAH
TITLE:
WRAPS - Capsule Cap Outlet Half
DWG. NO.
ADA-0045
SIZE
B
PART/MAT'L NO.
023-001
DOC REV.
00
DOG NO. 1
SHEET 1 OF 1


REVISIONS
REV
DESCRIPTION
INITIAL RELEASE
DATE
Drill #38 (0.102 DIA)
thru as shown
Drill #19 (0.166 DIA)
thru as shown
Drill #50 (0.07 DIA)
thru as shown
Drill #19 (0.166 DIA)
thru as shown
0.146
0.202
Ø0.938
Ø1.338 +.005
Ø2.0
Chamfer 0.03in
by 45 deg.
R0.13
0.15
0.300
0.239
Drill #7 (0.201 DIA) by
0.15 deg as shown
Drill #77 (0.018 DIA)
thru as shown
Chamfer 0.005in
by 45 deg.
DETAIL E
SCALE 4 : 1
37°
20°
0.84
0.213
E
0.129
0.84
45°
UNLESS OTHERWISE SPECIFIED
DIMENSIONS ARE IN INCHES
DECIMAL
ANG ±1°
SOLIDWORKS GENERATED DRAWING
DO NOT MANUALLY UPDATE
APPROVALS
DATE
Jason Moore
IPS
THIRD ANGLE PROJECTION
MATERIAL:
ALUMINUM
SPEC NO.
N/A
SCALE:2:1
DO NOT SCALE DRAWING
Department of Bioengineering
THE UNIVERSITY OF UTAH
TITLE:
WRAPS - Capsule Cap Injection Mold
DWG. NO.
ADA-0046
SIZE
B
PART/MAT'L NO.
024-001
DOC REV.
00
DOC NO.1
SHEET 1 OF 1

REVISIONS				
REV	DESCRIPTION	CCN	DATE	BY/CHKD/APPD
00	INITIAL RELEASE		9/23/10	TC / /
				/ /
				/ /
				/ /
				/ /





IPS

THIRD ANGLE PROJECTION

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.05
.XX ±.01
.XXX ±.005

ANG ±1°

MATERIAL:

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING, DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN T. COLEMAN	11/30/10
CHECKED	
APPROVED	

SCALE: 2:1
DO NOT SCALE DRAWING

Department of Bioengineering
THE UNIVERSITY OF UTAH

TITLE: WRAPS - ELECTRONIC PACKAGE

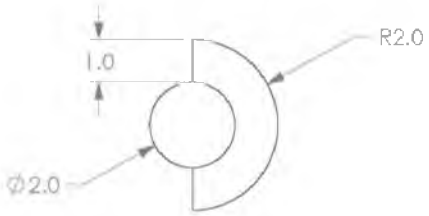
DWG. NO. ADA-0047

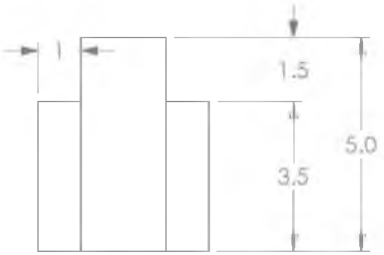
SIZE	PART/MAT'L NO.	DOC REV.
A	SEE SPEC.	00

DOC NO. 1 SHEET 1 OF 1

REVISIONS

REV	DESCRIPTION	CCN	DATE
00	INITIAL RELEASE	EV	9/16/12





UNLESS OTHERWISE SPECIFIED
DIMENSIONS ARE IN MILLIMETERS

MACHINED SURFACES

DECIMAL .X ±.05
.XX ±.01
.XXX ±.005

ANG ±1°

MATERIAL:

SPEC NO. N/A

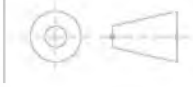
SOLIDWORKS GENERATED DRAWING.
DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN E.VANDERSTEEN	10/16/12
CHECKED	
APPROVED	

SCALE: 8:1
DO NOT SCALE DRAWING

MMGS

THIRD ANGLE PROJECTION



Department of Bioengineering
THE UNIVERSITY OF UTAH

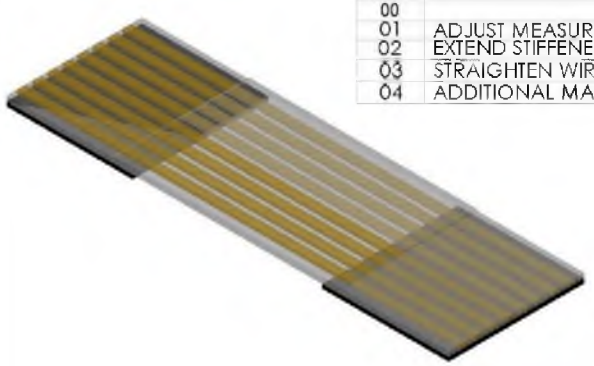
TITLE: COVER FOR BASE STATION LED

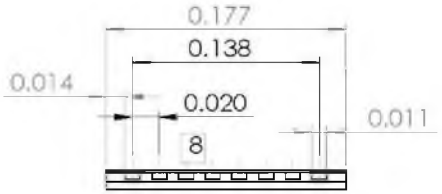
DWG. NO. ADA-0048

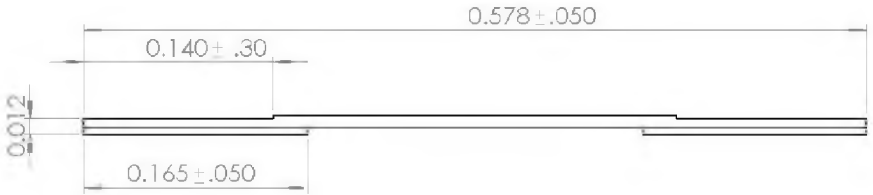
SIZE	PART/MAT'L NO.	DOC REV.
A	025-001	00

DOC NO. 1 SHEET 1 OF 1

REVISIONS			
REV	DESCRIPTION	CCN	DATE
00	INITIAL RELEASE	EV	10/16/12
01	ADJUST MEASURMENTS AND MODEL BASED ON MANUFACTURER	EV	10/30/12
02	EXTEND STIFFENER AND EXPOSED CONDUCTOR	EV	11/15/12
03	STRAIGHTEN WIRE, MANUFACTURER LENGTH TOLERANCE	EV	07/19/13
04	ADDITIONAL MANUFACTURER LENGTH TOLERANCES	EV	08/09/13

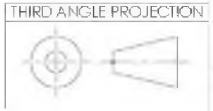






IPS

THIRD ANGLE PROJECTION



UNLESS OTHERWISE SPECIFIED
DIMENSIONS ARE IN INCHES

MACHINED SURFACES

DECIMAL .X ±.05
.XX ±.01
.XXX ±.005

ANG ±1°

MATERIAL:

SPEC NO. N/A

SOLIDWORKS GENERATED DRAWING,
DO NOT MANUALLY UPDATE

APPROVALS	DATE
DRAWN E.VANDERSTEEN	10/16/12
CHECKED	
APPROVED	

SCALE: 10:1
DO NOT SCALE DRAWING

Department of Bioengineering
THE UNIVERSITY OF UTAH

TITLE: WRAPS - RIBBON WIRE

DWG. NO. ADA-0045 DOC REV. 04

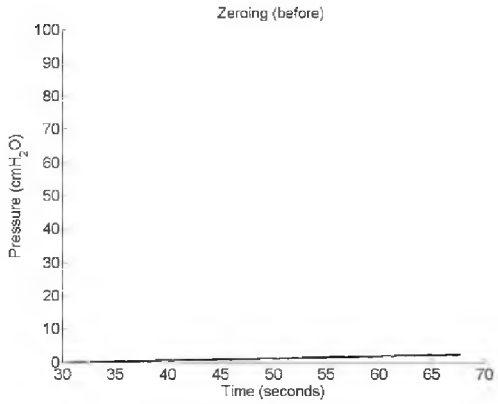
SIZE A | PART/MAT'L NO. 026-001 | DOC REV. 04

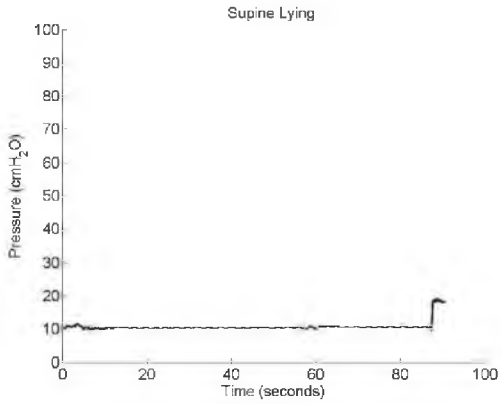
DOC NO. 1

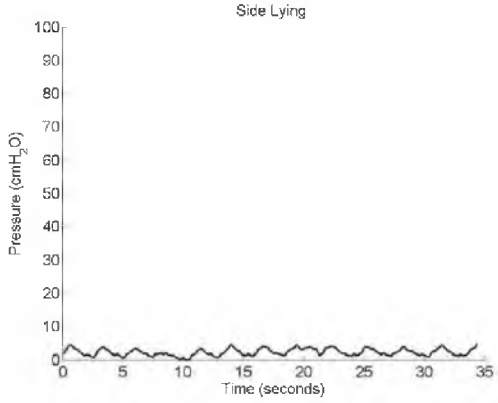
APPENDIX F

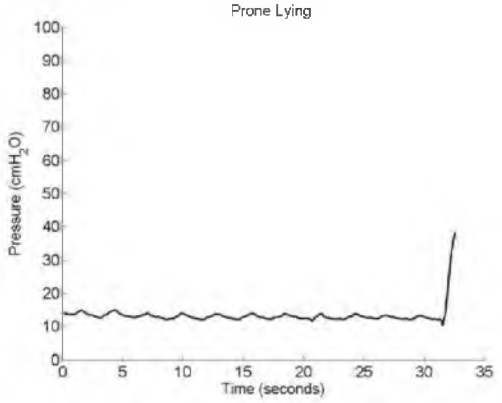
EXERCISE PHYSIOLOGY INTRA-ABDOMINAL

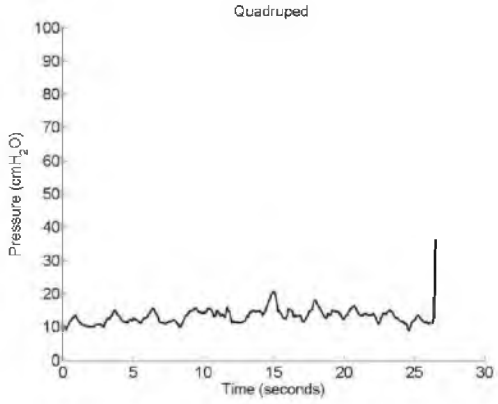
PRESSURE GRAPHS

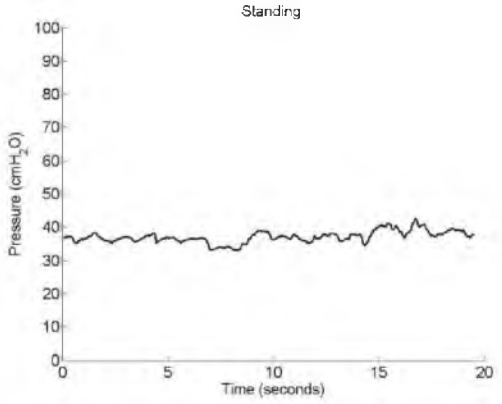

Zeroing (before)
Pressure (cmH2O)
Time (seconds)

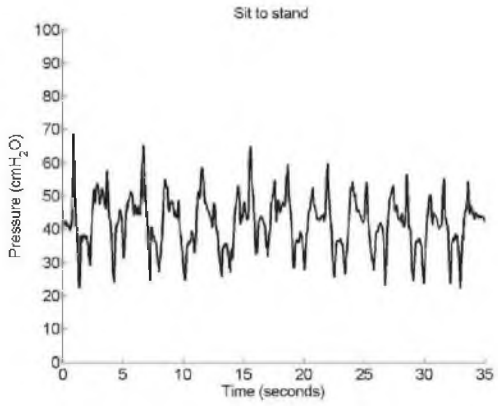

Supine Lying
Pressure (cmH2O)
Time (seconds)

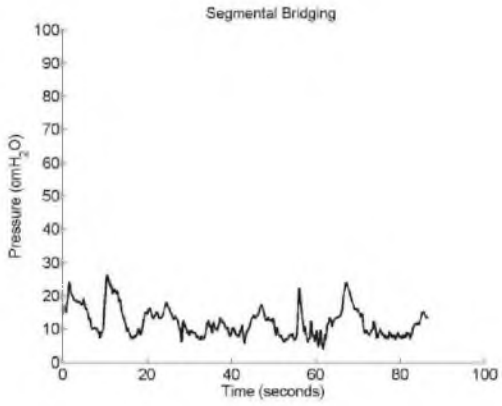

Side Lying
Pressure (cmH2O)
Time (seconds)

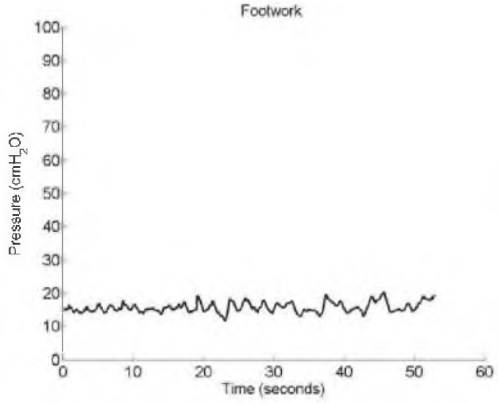

Prone Lying
Pressure (cmH2O)
Time (seconds)

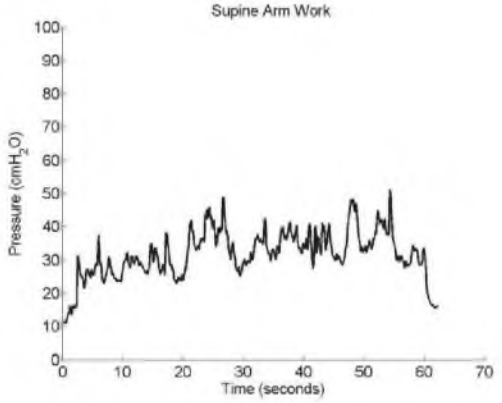

Quadruped
Pressure (cmH2O)
Time (seconds)

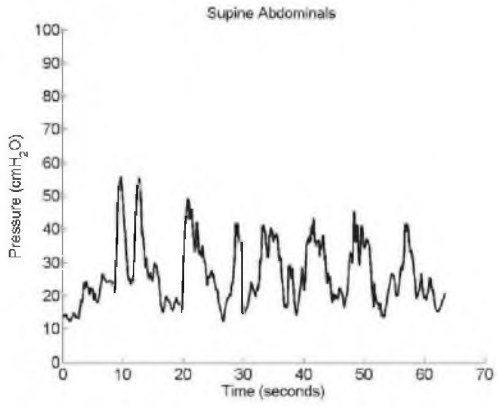

Standing
Pressure (cmH2O)
Time (seconds)

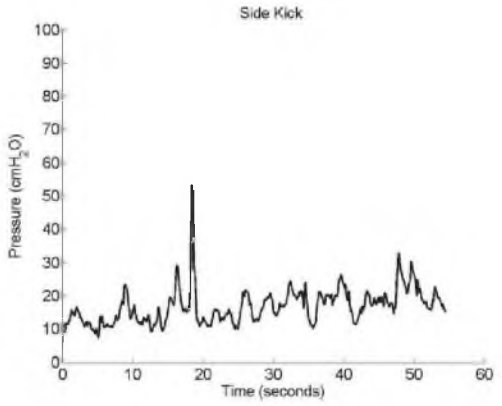

Sit to stand
Pressure (cmH2O)
Time (seconds)

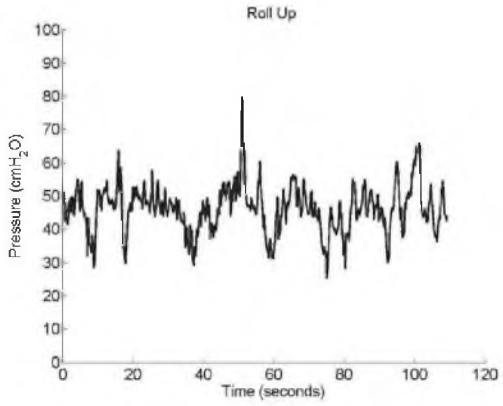

Segmental Bridging
Pressure (cmH2O)
Time (seconds)

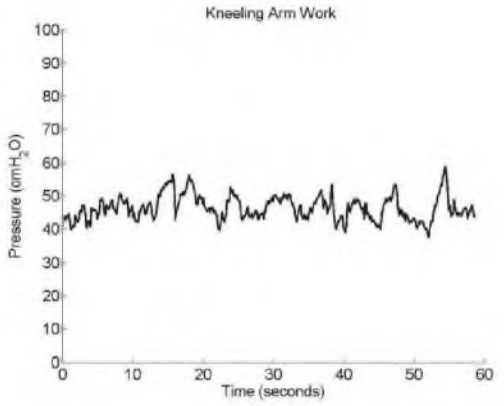

Footwork
Pressure (cmH2O)
Time (seconds)

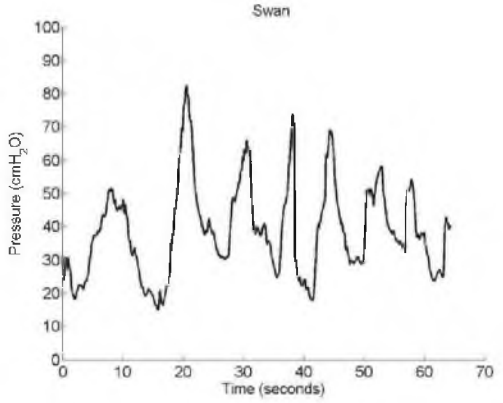

Supine Arm Work
Pressure (cmH2O)
Time (seconds)

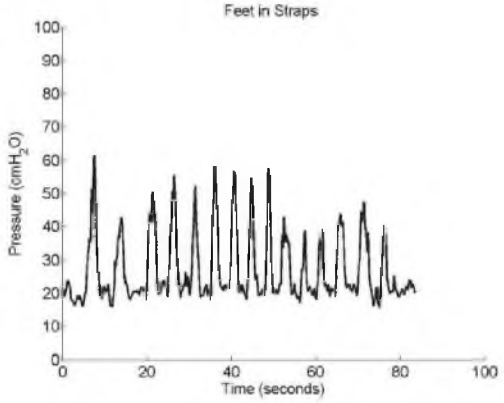

Supine Abdominals
Pressure (cmH2O)
Time (seconds)

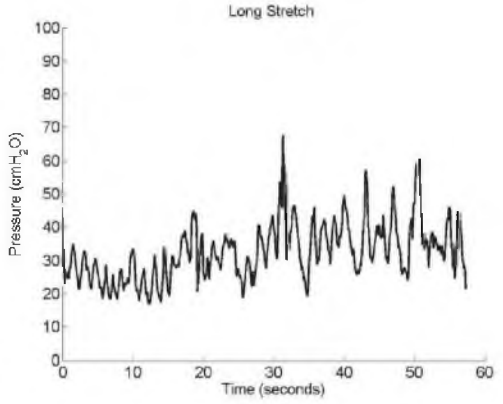

Side Kick
Pressure (cmH2O)
Time (seconds)

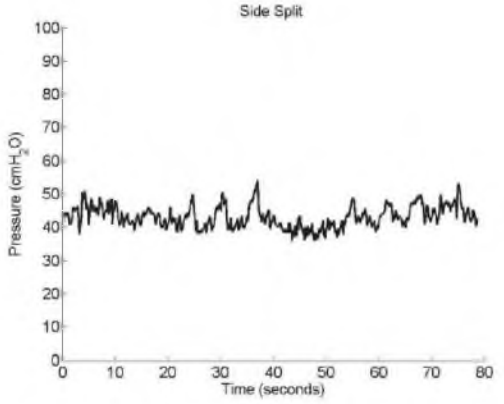

Roll Up
Pressure (cmH2O)
Time (seconds)

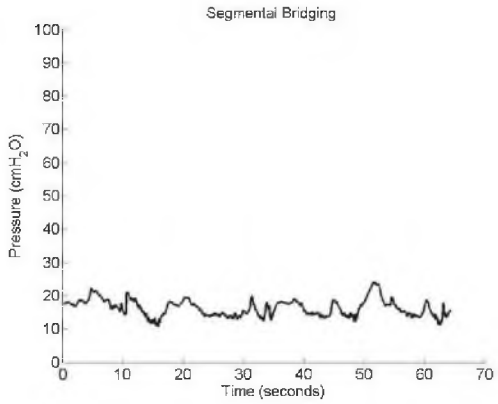

Kneeling Arm Work
Pressure (cmH2O)
Time (seconds)

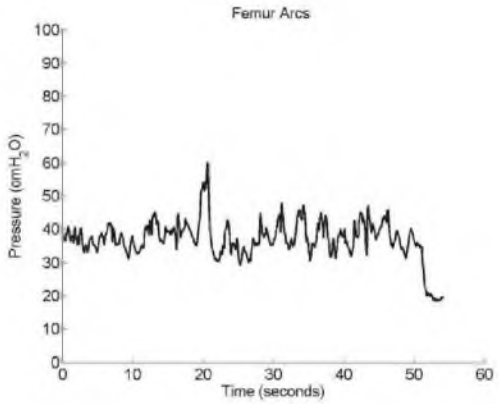

Swan
Pressure (cmH2O)
Time (seconds)

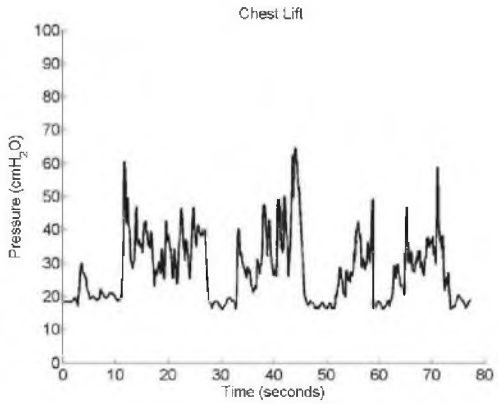

Feet in Straps
Pressure (cmH2O)
Time (seconds)

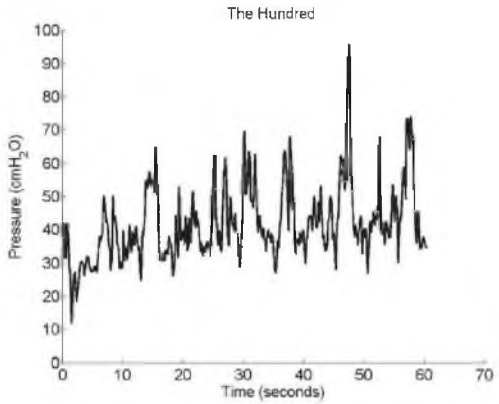

Long Stretch
Pressure (cmH2O)
Time (seconds)

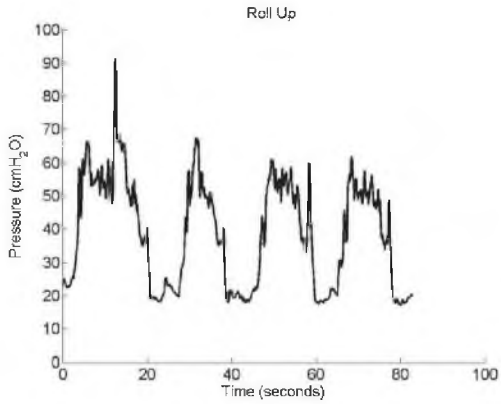

Side Split
Pressure (cmH2O)
Time (seconds)

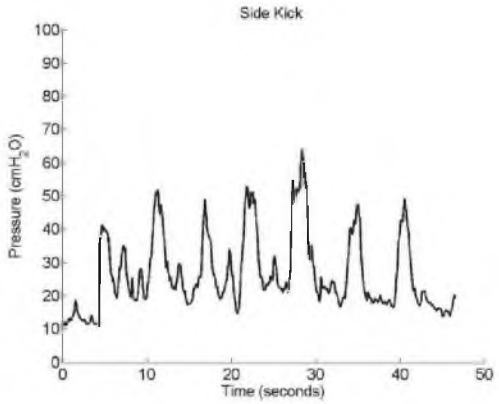

Segmental Bridging
Pressure (cmH2O)
Time (seconds)

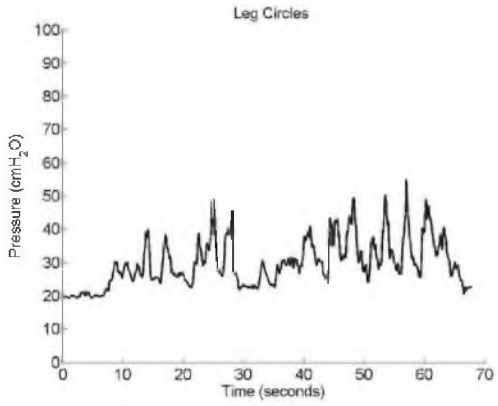

Femur Arcs
Pressure (cmH2O)
Time (seconds)

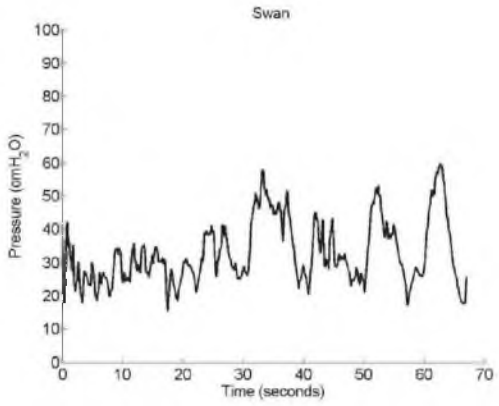

Chest Lift
Pressure (cmH2O)
Time (seconds)

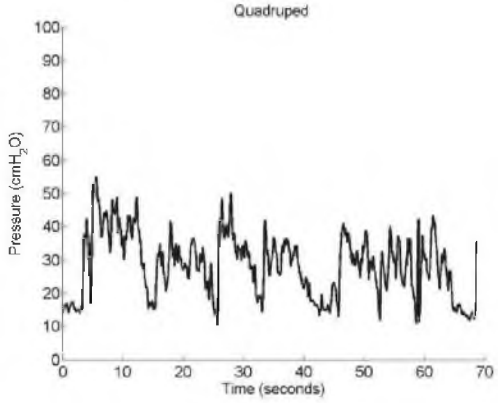

The Hundred
Pressure (cmH2O)
Time (seconds)

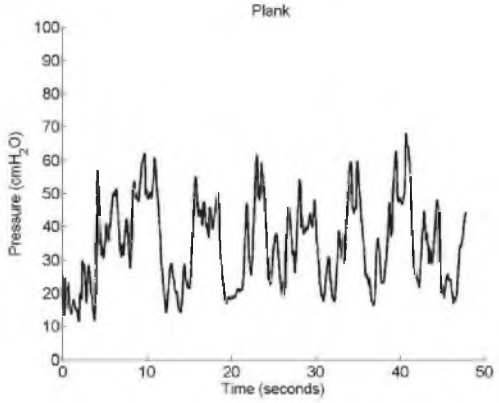

Roll Up
Pressure (cmH2O)
Time (seconds)

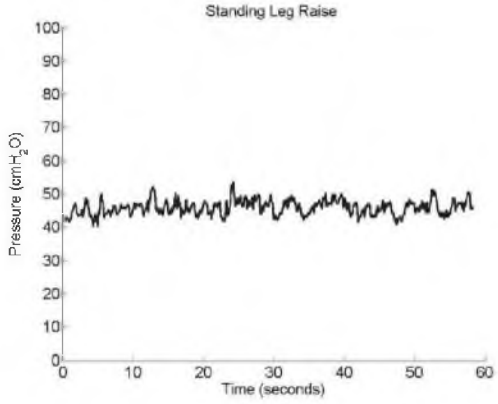

Side Kick
Pressure (cmH2O)
Time (seconds)


Leg Circles
Pressure (cmH2O)
Time (seconds)


Swan
Pressure (cmH2O)
Time (seconds)


Quadruped
Pressure (cmH2O)
Time (seconds)


Plank
Pressure (cmH2O)
Time (seconds)


Standing Leg Raise
Pressure (cmH2O)
Time (seconds)